

EPA REGISTRATION NUMBER 82669-2

Receipt for Section 3

S: 865406

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Miscellaneous Receipt

Billable: ☐ Yes ☒ No

Company: 82669 HOMES LLC

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82669-2

Product Name: BIO-UD-8 SPRAY

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 08-Jan-2010

OPP Rec'd Date: 08-Jan-2010

Front End Date: 12-Jan-2010

Risk Manager Send Date: 12-Jan-2010

FFS Due Date: 28-Apr-2010

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description: efficacy data

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

Signature Date:

Decision #: 426892

HOMS, LLC
 c/o Iain Weatherston, Ph.D.
 Technology Sciences Group, Inc.
 Arizona: Regulatory Division
 4061 North 156th Drive
 Goodyear, AZ 85338

FEB 02 2010

Dear Dr. Weatherston:

Subject: Response to Rebuttal Letter dated December 14, 2009
 Bio-UD-8 Lotion and Bio-UD-8 Spray
 EPA Reg. Nos. 82669-1 and 82669-2

The Biopesticides and Pollution Prevention Division (BPPD) is in receipt of your rebuttal letter to the Agency's letter dated December 14, 2009. BPPD has also received the copy of your rebuttal letter dated June 19, 2008, which you provided with your rebuttal letter dated December 14, 2009. We have reviewed your rebuttal letters and determined that the actions requested are not acceptable for the reasons stated below.

You indicated in your letter dated December 14, 2009 that, "The Agency is incorrect in believing 'Bite Blocker' is false and misleading, we agree that it implies a mode of action to block the biting of insects but the Agency is unlikely to be able to refute this." Also in your rebuttal letter dated June 19, 2008 you indicated that: 1) "At this time, nobody, not the Environmental Protection Agency, United States Department of Agriculture, Centers for Disease Control and even the National Academy of Sciences know 'the actual mode of action' of any arthropod repellent even DEET" and 2) "In summary, the mechanism or mode of action of insect repellents is not known to the Agency, in fact the current scientific opinion seems to favor a blocking of the arthropod olfactory system to human emitted attractive materials, but there are other possibilities, the oils in the spray and lotion could act as a physical barrier for a short time until the 'repellent' materials volatilize and the blocking of the olfactory system takes over." As indicated in your previous statements, the mode of action of these insect repellents is not known and you agreed with the Agency that the phrase "Bite Blocker" implies that the mode of action is to block the bite of insects. The Agency still believes that this term is false and misleading because you have not demonstrated that your products are blocking the bite of the insects. In order for you to use the term "Bite Blocker" on your labels, you must submit data that specifically demonstrates the blocking effectiveness of your products. If you are unable to submit this data, you must remove all mention of "Bite Blocker" from your labels.

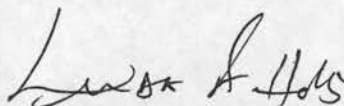
CONCURRENCES

MBOL	7511P	7511P					
IRNAME	Walsh	COLE					
DATE	1/26/10	1/27/10					

As stated in our previous letter dated December 14, 2009, before your next label printing, please revise the master label and final printed label in accordance with the changes directed above. Resubmit the new master label and final printed label prior to shipment of your product. Failure to make the directed changes will subject your client's registration to cancellation in accordance with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 6(e).

Should you have any questions, you may contact Colin Walsh directly at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda A. Hollis".

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

1/27/2010

Note to File

To: File Jackets 82669-1; 82669-2; and 82669-G

From: A. Bryceland, Team Leader, BPB

TSG, Inc. on behalf of HOMES, LLC submitted two data volumes concerning the above products on 1/8/09 (pin-punch date). These data volumes (MRIDs 479492-01 & -02) have not been reviewed. The application form (dated 1/8/2010) and cover letter (date 1/8/2010; MRID 479492-00) did not indicate what the registrant wished the Agency to do with these data. Contacted the registrant representative, Heather Bjornson of TSG, Inc., on 1/21/10 and inquired what they wish to do. She indicated that their client wanted them to submit this efficacy data to the Agency and that these data were not associated with any particular action. Since these data were not associated with any particular action the data will not be reviewed and the registrant's representative was informed of this by phone on 1/21/10. However, the registrant's representative was informed on 1/21/10 if the registrant does submit an action (for example an amendment), and the Agency needs to review the data, then that action would be classified as PRIA action because we would need to review these data.

Note that only one application form and the cover letter were submitted listing the following EPA File Symbol/Reg No. 82669-1; 82669-2; and 82669-G.

According to OPPIN, at the time this application was received the two products, 82669-1 and -2, did not have any pending amendments. Furthermore, these data were not requested for the pending section 3 registration, 82669-G.

These three submissions were classified as "Miscellaneous Receipt" in OPPIN since the registrant did indicate, by phone, that these data were not affiliated with any particular action, were therefore not reviewed. The submission was closed as "no response necessary" in OPPIN and the Decision was closed.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82669-1, 82669-2, 82669-G	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HOMS BioUD Insect Repellents	PM# BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) HOMS L.L.C P.O. Box 724 Clayton, NC 27520 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This submission is to provide additional efficacy data supporting the products: BioUD Lotion (EPA Reg. No. 82669-1), Bite Blocker BioUD Insect Repellent and Clothing Treatment (EPA Reg. No. 82669-2), Bite Blocker BioUD Clothing & Gear Insect Repellent (Pending as EPA File Symbol 82669-G).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted					
Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 6 oz.		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Silkscreen			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Heather R. Bjornson, Technology Sciences Group, Inc.	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 828-8945	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6 Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Assistant to HOMS L.L.C		
4. Typed Name Heather R. Bjornson	5. Date January 8, 2010		

**WASHINGTON**

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis
Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

January 8, 2010

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

**RE: BioUD Lotion (EPA Reg. No. 82669-1), Bite Blocker BioUD
Insect Repellent and Clothing Treatment (EPA Reg. No. 82669-
2), Bite Blocker BioUD Clothing & Gear Insect Repellent
(Pending as EPA File Symbol 82669-G)**

**Submission of efficacy data supporting HOMS L.L.C Insect
Repellent products**

Dear Linda:

Technology Sciences Group, on behalf of HOMS L.L.C., is submitting the enclosed efficacy data to support the above referenced HOMS L.L.C. product registrations.

Please do not hesitate to contact me with any questions at (202) 828-8945 or via e-mail: hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson
Regulatory Assistant to HOMS L.L.C.

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754

VOLUME 1 OF 3 OF SUBMISSION

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

HOMS L.L.C.
PO Box 724
Clayton, NC 27520

REGULATORY ACTION:

Submission of efficacy data supporting: BioUD Lotion (EPA Reg. No. 82669-1), Bite Blocker BioUD Insect Repellent and Clothing Treatment (EPA Reg. No. 82669-2), Bite Blocker BioUD Clothing & Gear Insect Repellent (Pending as EPA File Symbol 82669-G)

TRANSMITTAL DATE:

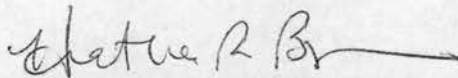
January 8, 2010

LIST OF SUBMITTED STUDIES:

MRID NUMBER	VOLUME NUMBER	EPA STUDY TITLE	OPPTS GUIDELINE NUMBER
	1 of 3	(Transmittal Document)	-----
47949201	2 of 3	Tick Repellents: Past, Present, and Future	810.3700
47949202	3 of 3	Comparative Efficacy of BioUD to Other Commercially Available Repellents against the Ticks <i>A. americanum</i> and <i>D. variabilis</i>	810.3700

COMPANY NAME: HOMS L.L.C.

COMPANY OFFICIAL:



Heather R. Bjornson, Regulatory Assistant to HCMS L.L.C.

COMPANY CONTACT:

Heather R. Bjornson
Technology Sciences Group Inc.
1150 18th Street NW, Suite 1000
Washington, D.C. 20036
Direct dial (202) 828-8945; Email: hbjornson@tsgusa.com



Re: Bio-UD-8 Lotion and Spray (EPA Reg. Nos. 82669-1 and -2)

IAIN WEATHERSTON to: Colin Walsh

12/15/2009 12:48 AM

Cc: Lily Negash

Colin:

Since the branding name "Bite Blocker" is very important to my client and has been used on non-FIFRA regulated products for many years as well as the BioUD products for the last two or three I believed today's letter required an immediate response since it is obvious that there are documents missing from your HOMS files and you are making decisions with incomplete information.

The attachments for your review (from left to right above) are

The letter of rebuttal to Linda's December 14, 2009 letter

The letter of rebuttal to the two June 03, 2008 letters

A copy of Linda's letter of today.

If you require further information, or have any questions please do not hesitate to contact me at jazkatz@qwestoffice.net or by phone at 623-535-4060

Regards,

Iain

----- Original Message -----

From: <Walsh.Colin@epamail.epa.gov>

To: <jazkatz@qwestoffice.net>

Cc: <Negash.Lily@epamail.epa.gov>

Sent: Monday, December 14, 2009 10:22 AM

Subject: Bio-UD-8 Lotion and Spray (EPA Reg. Nos. 82669-1 and -2)

>

> Dr. Weatherston,

>

> BPPD is in receipt of your two notifications dated September 1, 2009 for
> the above products as requested by PRSB/FEAD in an email dated September
> 1, 2009. BPPD has reviewed the notifications and has determined that the
> notifications are unacceptable. Please see the attachments of the
> deficiency letters and let me know if you have any questions. A hardcopy
> has been mailed to you. I have also included PRSB/FEAD on this email.

>

> Thanks,

>

> Colin

>

> (See attached file: Deficiency Letter dated 12-14-09 (82669-1 and
> -2).pdf) (See attached file: Deficiency Letter dated 6-3-08
> (82669-1).pdf) (See attached file: Deficiency Letter dated 6-3-08
> (82669-2).pdf)

>

>

> Colin G. Walsh

> Biologist, Biochemical Pesticides Branch

> Biopesticides and Pollution Prevention Division (7511P)

> Office of Pesticide Programs

> U.S. Environmental Protection Agency

> walsh.colin@epa.gov

> (703) 308-0298 (phone)

> (703) 305-0118 (fax)

> <http://www.epa.gov/pesticides/>

>



----- 061908rebuttallletter.pdf 121409letter from EPA.pdf 121409rebuttall letter.pdf

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX: (623) 535-4061
E-Mail: jazkatz@qwestoffice.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Colin G. Walsh
Biologist, Biochemical Pesticides Branch
U.S. EPA - OPP - BPPD (7511P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

December 14, 2009

SUBJECT: Rebuttal of EPA letter dated December 14, 2009 regarding Notification of alternate brand names for Bio-UD-8 products 82669-1 and 82669-2.

COMPANY: HOMS LLC

CONTACT: Iain Weatherston, Ph.D., Technology Sciences Group Inc., 4061 North 156th Drive, Goodyear, AZ 85395

Dear Colin:

First of all I wish to acknowledge receipt of the following documents and thank you for affording me a "heads up" on the later delivery by US mail.

December 14, 2009 letter over Linda Hollis signature relative to both HOMS products
June 03, 2008 letter over Linda Hollis signature relative to 82669-1
June 03, 2008 letter over Linda Hollis signature relative to 82669-2

Regarding the December 14, 2008 letter

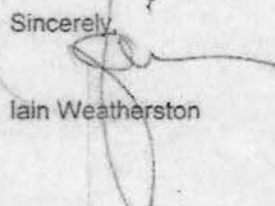
The Agency is incorrect in believing "Bite Blocker" is false and misleading, we agree that it implies a mode of action to block the biting of insects but the Agency is unlikely to be able to refute this.

The decision to approve Bite Blocker BioUD as a branding was correctly made by the Agency in notification dated January 8, 2009 and October 26, 2009 and any further review which determined that these names are unacceptable is contrary to the evidence and arguments sent to the Agency on June 19, 2009 in a letter of rebuttal of the June 03 letters. There is no mention of this letter in Ms. Hollis's December 14 letter. In fact a response to the rebuttal was never received. A copy of this June 19, 2008 rebuttal letter is attached to this letter along with Pesticide Application form filed at that time together with FedEx tracking details showing that the rebuttal letter was delivered to One Potomac Yard at 10:27 am on June 20, 2008 and signed for by someone with the name, D. Allen. (The June 03, 2008 letters noted in the attachments of my June 19, 2008 are not included in the current package).

Please note the first two sentences in the final paragraph of the June 19, 2008 letter *"It would appear that there are documents missing from your HOMS files. I can back up everything that is in the letter with documentation."*

Once you have reviewed the June 19, 2009 rebuttal letter and find and review the other missing documents I would like to receive a letter retracting the Agency's decision that "Bite Blocker" is unacceptable and false and misleading.

Sincerely,


Iain Weatherston

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticide and Pollution Prevention Division
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

June 19, 2008

SUBJECT: Rebuttal to Agency Letters dated June 3, 2008

COMPANY: HOMES LLC.,
P.O. Box 724
Clayton Center, Clayton, N.C. 27520

CONTACT: Iain Weatherston
Technology Sciences Group Inc.
[Contact information as per letterhead]

PRODUCTS: Bio-UD 8 Lotion [82669-1] and Bio-UD 8 Spray [82669-2]

Dear Ms. Hollis:

I am in receipt of two letters dated June 3, 2008, over your signature. The letters are identical, one referring to the lotion product and the second referring to the spray product. A copy of the letters is attached. On behalf of HOMES LLC, the registrant of these mosquito and tick products I am submitting this rebuttal to the changes which we are being asked to make to the product labels. The order of our response is the same as that in both Agency letters.

BITE BLOCKER [1]

"The brand name 'Bite Blocker' is not acceptable as the term blocker suggests the products mode of action is to block the biting of the insects" A few sentences later you say "Since repelling is the mode of action of the product, this brand name would be considered false or misleading."

At this time, nobody, not the Environmental Protection Agency, United States Department of Agriculture, Centers for Disease Control and even the National Academy of Sciences know "the actual mode of action" of any arthropod repellent even DEET. This is currently a very active research area for many universities and government agencies. For example the USDA/ARS has an ongoing research project "Manipulation of Arthropod Behavior for Protection of Humans" [Proj. #1275-32000-001-00], of which the third objective is to "identify the mechanisms underlying the activity of key mosquito repellents and attractants, and develop ways to exploit the mechanisms for commercial use."

In August 2005, Dr. Alexandra Connelly Frost writing a scholarly article in AHC Media's "Hot Topics" on the subject of Oil of Lemon Eucalyptus as an insect repellent states (after quoting

several scientific articles), "Curiously, none of the above articles discussed the mechanism by which PMD repels insects. The mode of action of many repellents is unclear, but it is believed that these products do not repel insects, they simply mask or confuse the attractive signals that humans emit so that mosquitoes are unable to locate us. Mosquitoes have specific sensory receptors that provide them with the information they need to detect a source, orient to it and travel to it to sample a blood meal."

Also in a recent edition of Science Express (March 13, 2008) and in Science (March 28, 2008) there is an article from the Laboratory of Neurogenetics and Behavior at the Rockefeller University in New York entitled "Insect Odorant Receptors are Molecular Targets of the Insect Repellent DEET" by Mathias Ditzgen, Maurizio Pellegrino and Leslie B. Vosshall. In the abstract of the article they state "DEET is the world's most widely used topical insect repellent, with broad effectiveness against most insects. Its mode of action and molecular target remain unknown. Here, we show that DEET blocks electrophysiological responses to olfactory sensory neurons to attractive odors in *Anopheles gambiae* and *Drosophila melanogaster*. The summary ends with "We conclude that DEET masks the host odors by inhibiting subsets of heteromeric insect odorant receptors that require OR83b co-receptor. The identity of candidate molecular targets for the action of DEET may aid in the design of safer and more effective insect repellents."

Ongoing research at Rothamsted Research Centre in England is focused on why some people are attractive to mosquitoes while others appear not to be. The results of their investigations "suggest that differential attractiveness is due to compounds in unattractive individuals that switch off attraction either by acting as repellents or by masking the attractant components of human odour."

The next criterion we should consider is that both mosquitoes and ticks (but not wasps and bees) need to be standing on the skin to bite. Mosquitoes, unlike bees and wasps, cannot bite (sting) while hovering. In some of the screening and testing of candidate repellent compounds the "arm-in-cage" study method is used. In this type of study the compounds are scored by the number of mosquito landings on the exposed arm in a given time period. So the attack of a mosquito may be said to occur by (1) attraction to host, (2) orientation to host, (3) travel to the host (4) landing on host and then (5) biting the host. So anywhere in the sequence 1 → 2 → 3 → 4 should an event happen that disrupts the sequence then we have stopped, inhibited or blocked the mosquito from biting. The Webster dictionary has 35 different meanings for the word "block," three are relevant (i) a stoppage in or difficulty in proceeding with processes usually mental, (ii) to obstruct by placing obstacles in the way, (iii) to stop the passage of impulses in a nerve.

In summary, the mechanism or mode of action of insect repellents is not known to the Agency, in fact the current scientific opinion seems to favor a blocking of the arthropod olfactory system to human emitted attractive materials, but there are other possibilities, the oils in the spray and lotion could act as a physical barrier for a short time until the "repellent" materials volatilize and the blocking of the olfactory system takes over.

Based on the above we believe that "Bite Blocker" is not false nor misleading. It is used as branding strategy for HOMS mosquito control products both those that fall under the jurisdiction of FIFRA and those exempt from FIFRA.

BITE BLOCKER [2]

This alternate brand name "Bite Blocker" was proposed to EPA via a notification on 5/22/07 and this notification was denied by EPA on 6/19/07. EPA has not received another notification or

amendment application regarding an alternate brand name since that time. To date, the alternate brand name has not been approved by EPA.

The above statements are not factual

- 1] The statement that the Bite Blocker alternate brand name was proposed by notification on 5/22/07 is correct. (Actually it was May 2).
- 2] Your letters of June 19, 2007 (one for each product) did deny the Notification but it did not indicate that Bite Blocker was not acceptable. The reasons for the denial of the notification was that there were four actions and the Agency deemed it to be an amendment and you asked that it be resubmitted as such. In your June 19 letters as regards to the alternate brand name, nowhere does it say that it is unacceptable.
What it says is that I did not follow the directions in PRN 98-10 and only submitted a label with the alternate brand name whereas I should have submitted labels with the base name the one on the SAL and the alternate name.
- 3] On June 20, 2007 I prepared two letters of Notification (one for each product), these were couriered to the Notification Coordinator (BPPD) on June 21 and were delivered to the Agency at 11.25 am on Tuesday June 22 and signed for by D. Allen. The statement that you never received a Notification or Amendment after you June 19, 2007 is patently wrong. This notification indicated that HOMS LLC was desirous of marketing the two products as:

Bite Blocker® BioUD™ INSECT REPELLENT 1

&

Bite Blocker® BioUD™ INSECT REPELLENT AND CLOTHING TREATMENT

The notification also contained verbiage to consolidate two tick claims into

Repels ticks that may transmit Lyme Disease and Rocky Mountain Spotted Fever for up two hours

LABEL CLAIMS

The June 3rd letter continues "*The claim "Protects against mosquito borne diseases for 4.5 hours" cannot be allowed as this claim may be interpreted as the product providing immunity to disease not repellency against biting insects"*

The Claim "Repels ticks and mosquitoes that may transmit Lyme Disease cannot be allowed" as mosquitoes do not transmit that disease. The claim is acceptable if "and mosquitoes" is removed.

These two sentences are inaccurate and puzzling for the following reasons:

- 1] The last iteration of the draft label for each product, submitted on June 21/22 carried only two marketing claims, namely:
"Repels mosquitoes that may carry West Nile Virus for up to 4.5 hours"
"Repels ticks that may transmit Lyme disease and Rocky Mounted Spotted Fever for up to 2 hours.

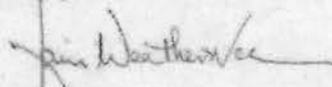
These labels would constitute the labels of record of each product and would

supercede any previous label.

- 2] On July 29th 2007, more than 30 days after the submission of the Notification on June 21/22, 2007 final printed labels were submitted with a cover letter and a fully executed pesticide application form EPA Form 8570-1. These final printed labels reflected the draft labels submitted on June 21/22. This package was addressed to Ms Linda Hollis c/o Document Processing Desk; it was delivered to the Agency at 9.12 am on August 1, 2007 and signed for by A. Kea (I must admit the signature looks illegible to me).

It would appear that there are documents missing from your HOMS files. I can back-up everything that is in this letter with documentation. Should you require further information or have any questions please contact me at jazkatz@qwestoffice.net or by telephone at 623-535-4060.

Sincerely yours,



Iain Weatherston

attachments: June ⁰³18, 2008 letter re Bite Blocker® BioUD™ INSECT REPELLENT 1
[82669-1] ⁰³
June ⁰³18, 2008 letter re Bite Blocker® BioUD™ INSECT REPELLENT AND
CLOTHING TREATMENT [82669-2]
Application for pesticide registration [EPA Form 8570-1]

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

HOMS, LLC
c/o Iain Weatherston, Ph.D.
Technology Sciences Group, Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338

DEC 14 2009

Dear Dr. Weatherston:

Subject: Bio-UD-8 Lotion and Bio-UD-8 Spray
EPA Reg. Nos. 82669-1 and 82669-2
Application for Label Notification dated September 1, 2009 to add
alternate brand names.

The Biopesticides and Pollution Prevention Division is in receipt of your application for a Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested is **not acceptable** for the reasons below:

1. As indicated in the Agency's deficiency letters for the above products dated June 3, 2008, the brand name "Bite Blocker" is not acceptable as the term "blocker" suggests the product's mode of action is to block the biting of insects. Use of the term would necessitate the submission of additional data demonstrating the blocking effectiveness of the product. PR Notice 98-10 allows the addition of alternate brand names by notification, but states that brand names may not be false or misleading. Since repelling is the actual mode of action of the products, these proposed brand names would be considered false or misleading. I have enclosed the Agency's deficiency letters dated June 3, 2008 for your reference.
2. In a review of the Agency's records, it was determined that the two alternate brand names, (1) Bite Blocker BioUD Insect Repellent and (2) Bite Blocker BioUD Clothing & Gear Insect Repellent, for the Bio-UD-8 Spray product were approved in the Agency notification letter dated January 8, 2009. The third alternate brand name, (3) Bite Blocker BioUD Insect Repellent and Clothing Treatment, for the Bio-UD-8 Spray product was approved in the Agency notification letter dated October 26, 2009. After further review, the Agency has determined that these three alternate brand names are unacceptable and the Agency's notification letters dated January 8, 2009 and October 26, 2009 are rescinded. As stated above, you must submit additional data demonstrating the blocking effectiveness of the products in order to use the term "blocker".

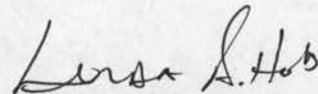
SYMBOL	7611P						
JRNAME	Walsh						
ATE	12/1/09						

Before your next label printing, please revise the master label and final printed label in accordance with the changes directed above. Resubmit the new master label and final printed label prior to shipment of your product.

Failure to make the directed changes will subject your client's registration to cancellation in accordance with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 6(e).

For any questions you may have concerning this action, please contact Mr. Colin Walsh at (703) 308-0298 or via email at walsh.colin@epa.gov.

Sincerely,

A handwritten signature in dark ink, appearing to read "Linda A. Hollis". The signature is fluid and cursive, with the first name "Linda" being more prominent.

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 26, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Iain Weatherston
Senior Regulatory Consultant
HOMS LLC.,
P.O. Box 724
Clayton, NC 27520

RE: Product Name: Bio-UD-8 Spray
EPA Reg. No: 82669-2
Application for Label Notification Dated October 12, 2009 to make Bite
Blocker® BioUD™ Insect Repellent and Clothing Treatment the Active
brand name and retaining Bio-UD-8 Spray as an alternate brand name

Dear Mr. Weatherston:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under Pesticide Registration (PR) Notice 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PR Notice 98-10 and it has been determined that the action(s) requested falls within the scope of PR Notice 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

If you have any questions concerning this action, please feel free to contact Ms. Menyon Adams at (703) 347-8496 or email at adams.menvon@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

Receipt for Section 3

S: 857541

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 82669 HOMS, LLC

V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82669-2

Product Name: BIO-UD-8 SPRAY

Override#:

Me Too Section3:

Me Too Product Name:

Application Date: 01-Sep-2009

ie

OPP Rec'd Date: 04-Sep-2009

ie

Front End Date: 04-Sep-2009

ie

Risk Manager Send Date: 08-Sep-2009

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Notification

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

New Ingredient Request Date:

New Ingredient Received Date:

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content

Des

Other

Notification.

View/Edit

Print Letter

Enter More Information

Tracking

Rec'd
SEP 10 2009
ACB 19



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82669-1	2. EPA Product Manager Linda Hollis / 91	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HOMS LLC/ Bite blocker Bio-UD 8 lotion	PM# BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) HOMS LLC, P.O. Box 724, Clayton, NC 27520 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated <u>Jan 6, 2009</u>	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is the application form and certification for a notification filed on June 20, 2007 and misplaced by the Agency. The notification was of an additional brand name and minor verbiage changes. For certification see separate page

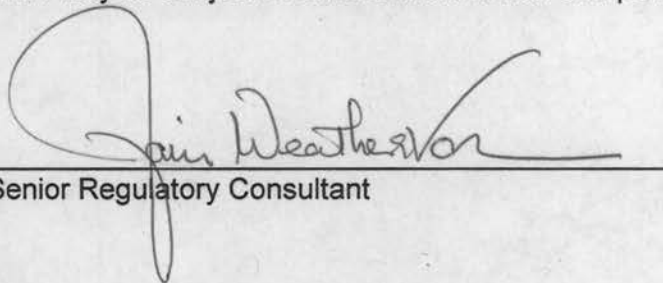
Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
certification must submitted	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container		<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container see separate sheet		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Iain Weatherston		Title Senior Regulatory Consultant		Telephone No. (Include Area Code) (6230-535-4060)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Regulatory Consultant			
4. Typed Name Iain Weatherston		5. Date September 1, 2009			

This notification is consistent with the provisions of PRN 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of the product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to wilfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



Jim Weatherston

Senior Regulatory Consultant

September 1, 2009

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwestoffice.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Ms. Linda Hollis
Chief, Biochemicals Branch
U.S. EPA - OPP - BPPD
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

September 1, 2009

SUBJECT: Notification being sent to BPPD as requested by PRSB/FEAD in an e-mail dated September 1, 2009.

COMPANY: HOMS LLC, Box 724 Clayton, NC 27520

CONTACT: Iain Weatherston, Ph.D., Technology Sciences Group Inc.
[Contact information as per letterhead]

PRODUCTS: Bio-UD-8 Lotion [82669-1]/Bio-UD-8 Spray [82669-2]

Dear Linda:

This notification package is being sent to you at the request of Lily Negash in PRSB/FEAD and the attachments offer an explanation. As you know the Agency plans to launch a website to provide the public with expanded repellent information. HOMS wishes to participate in this website with their two (currently registered, a third in review) 2-undecanone based mosquito and tick repellents. As you will see from William Diamond's August 17th letter the Agency is claiming that the alternate name Bite Blocker BioUD was never registered with EPA.

Bio-UD-8 Lotion [82669-1]

As you will see further, in my August 28 response to Ms. Negash I challenged this assertion since the alternate marketing name was submitted (twice) to the Agency as a notification.

Today, Ms. Negash has requested that I send the previous notification documentation so attached are (best copy) of the May 2, 2007 submission and the cover letter and the draft label from the June 20, 2007 submission.

Bio-UD-8 Spray [82669-2]

In her e-mail today Ms. Negash also requested I file a notification to "remove" the product name Bio-UD-8-Spray. I have not done so since Bio-UD-8 Spray is the base name by which the EPA knows the products and which is used in the EPA databases and so I do not know how it can be "removed." The solution is probably to leave the name in the table on the EPA website, even although the product is not marketed under that name. I would like BPPD's input into the concept of "removal" of a product name especially since it is the base name of the product.

Enclosure with this letter are:

September 1, 2009 e-mail (Negash - Weatherston)
August 25, 2009 Response to August 17, 2009 EPA letter (Weatherston - Negash)
August 17, 2009 EPA letter to HOMS LLC.
Copy of June 20, 2007 notification of additional brand name and minor verbiage changes and including the draft label submitted at that time.
Copy of May 2, 2007 notification and all attachments
Copy of screen from NPIRS Public database showing base names of HOMS products.
Application for Pesticide Registration form with certification, dated for today but in reference to June 20, 2007 notification which cannot be found at EPA.

Linda, if you have any questions or require further information, please do not hesitate to contact me by phone or e-mail.

Sincerely,

COPY
Iain Weatherston

cc: [w/o enclosures except June 20, 2007 notification letter and draft label]
Lily Negash [EPA-FEAD-PRSB]

IAIN WEATHERSTON

From: <Negash.Lily@epamail.epa.gov>
To: "IAIN WEATHERSTON" <jazkatz@qwestoffice.net>
Sent: Tuesday, September 01, 2009 9:05 AM
Attach: FAQs_Insect Repellent Website.doc; Repellenrwebpage response 082809.pdf
Subject: Regarding Your Response to August 17 letter re website.

Dear Dr Weatherston:

Thank you for your response. I thought I would let you know the status of your product list according to our records.

Lines 4 and 5 - active ingredient name - has now been changed to 2-undecanone.

Line 5 - product name - only one label submission found for EPA registration 82669-1 in our records. On 03/15/07 a notification from EPA to revise your label with EPA registration # 82669-1 before shipment of product. On 11/02/07, an acknowledgement of your 06/20/07 letter from EPA to change verbiage and to add brand name. However, documentation or label could not be found specifying the name "Bite Blocker BioUD Insect Repellent 1" as the name to be added. Please provide the appropriate division with a copy of this document and label - and copy me so that I can help follow up.

Line 4 - product name - Three names were added as alternate names to EPA registration # 82669-2 per your requests dated 06/19/07 and 12/15/08. However, documentation could not be found showing a request to "remove" the product name BIO-UD-8 Spray. Please see FAQ # 4 in the FAQ document attached below to request a product name removal so that your records can be updated.

EPA	Product Name		Company	Active	%	Protectio	Protectio
			Ingredient		n Time	n Time	Registratio
					for	for	n #
					Mosquitoe	Ticks	
				s			
-----+-----+-----+-----+-----+-----+-----							
2	Bite Blocker BIO-UD Insect Repellent and		HOMS LLC	2-undecanon	7.75	4.5	
	82669-2						
	Clothing Treatment		e				
-----+-----+-----+-----+-----+-----+-----							
2	Bite Blocker BioUD Insect Repellent		HOMS LLC	2-undecanon	7.75	4.5	
	82669-2						
			e				
-----+-----+-----+-----+-----+-----+-----							
2	Bite Blocker BIO-UD Clothing & Gear		HOMS LLC	2-undecanon	7.75	4.5	
	82669-2						
	Insect Repellent		e				
-----+-----+-----+-----+-----+-----+-----							

-----|
|08/30/2009 09:06 PM |
>-----

-----|
|----->
|Subject: |
|----->
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-----|
|Response to August 17 letter re website. |
>-----
-----|

Dear Ms. Negash:

Please find attached the response on behalf of HOMES LLC, to the August 17, 2009 letter over William Diamond's signature regarding the website for skin applied insect repellents.

Regards,

Iain

Dr. Iain Weatherston,
Technology Sciences Group Inc.
4061 North 156th Drive,
GOODYEAR, AZ 85395
623-535-4060 T

jazkatz@qwestoffice.net.

Head Office:

1150 18th Street N.W., Suite 1000
WASHINGTON, D.C. 20036
202-223-4992

www.tsgusa.com(See attached file: Repellenrwebpage response 082809.pdf)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 17, 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CERTIFIED MAIL

HOMS, LLC
TECHNOLOGY SCIENCES GROUP
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338

Dear Homs, LLC:

In early June, 2009, the Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) sent out letters to registrants of skin-applied insect repellents. The letter informed registrants of the Agency's plans to launch a website to provide the public with expanded insect repellent information. We appreciate the feedback we received from you in response to this letter. Enclosed is a Frequently Asked Questions (FAQs) document we developed based on requests we received from registrants following our June letter.

We have reviewed the information you sent in your June 10 letter and updated our product list. The list has been changed to reflect the correct company name of HOMS LLC, to change the active ingredient name to 2-undecanone, and to show an alternate product name of Bite Blocker BIO-UD Insect Repellent & Clothing Treatment under registration number 82669-2.

- ✓ Our records do not show a Notification to add alternate product name "Bite Blocker BIO-UD-8 Insect Repellent 1" for BIO UD-8 Lotion (registration number 82669-1). Please submit a notification to add or to change the name as shown in the attached FAQs # 3 and # 4.

As described in the previous letter, the OPP's insect repellent information website is consistent with EPA's renewed commitment to transparency and public outreach. This website will provide consumers with publicly available data to help them make better informed risk management decisions to protect themselves from vector-borne disease. In addition, the website will briefly discuss the use and effectiveness of skin-applied insect repellents and provide a list of EPA registered products. It will help the public learn more about vector-borne diseases such as Lyme disease and West Nile Virus, and how to choose an insect repellent product.

The Agency intends to launch the website in early fall of 2009. The insect repellent product list on the website will include all active, EPA-registered, skin-applied insect repellents, including those which are supplemental distributor products. This website will allow users to sort the product list by company name, product name, and EPA registration number. Each product will

show the active ingredient, the percentage of active ingredient in the formulation, and the hourly protection times from mosquitoes and ticks claimed by the product.

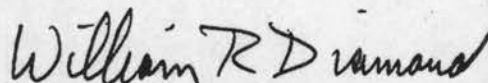
In response to comments made on the draft tables sent to registrants in June, EPA has modified the way in which the protection times for products without label-approved protection times will be displayed. An asterisk (*) will be used in these instances to indicate that EPA has technical information on the effectiveness of the product against mosquitoes and/or ticks and the company chose not to have a specific time associated with their product.

Consistent with program requirements, all revisions to product names, hourly protection times, and other product-specific information must be conducted through the label amendment review process. These actions fall under the Pesticide Registration Improvement Renewal Act (PRIA 2).¹ For more information, please contact the registration ombudsman, visit the EPA web page on PRIA 2, or see Chapter 4, Section III of the Label Review Manual².

We have enclosed a copy of the list of insect repellent products registered by your company. Please verify whether the information matches your submission records. If you have any questions, please contact Lily Negash, one of my staff, within ten business days following receipt of this letter. Lily can be reached by e-mail at negash.lily@epa.gov or by telephone at (703) 347-8515.

Thank you for your prompt attention to this matter and do not hesitate to contact me directly if I can be of assistance.

Sincerely,



William R. Diamond, Director
Field and External Affairs Division

Enclosures: List of Insect Repellent Products
Frequently Asked Questions

¹ Pesticide Registration Improvement Renewal Act (PRIA 2) Tables - FY 2009/FY 2010 Fee Schedule for Registration Applications
<http://www.epa.gov/pesticides/regulating/fees/tool/category-table.html>

² <http://www.epa.gov/oppead1/labeling/lrm/chap-04.htm#IIID>

LIST OF ACTIVE EPA REGISTRATIONS[†]: SKIN-APPLIED INSECT REPELLENT PRODUCTS

List of Products and Protection Times Claimed Against Mosquitoes and Ticks:

Product Name	Company	Active Ingredient	%	Protection Time for Mosquitoes	Protection Time for Ticks	EPA Registration #
Bite Blocker BIO-UD Insect Repellent and Clothing Treatment	HOMS LLC	2-undecanone	7.75	4.5	2	82669-2
Bite Blocker BioUD Insect Repellent	HOMS LLC	2-undecanone	7.75	4.5	2	82669-2
Bite Blocker BIO-UD Clothing & Gear Insect Repellent	HOMS LLC	2-undecanone	7.75	4.5	2	82669-2
BIO-UD-8 Spray	HOMS LLC	Methyl ketone	7.75	4.5	2	82669-2
Bite Blocker BioUD-8 Lotion	HOMS LLC	Methyl ketone	7.75	4.5	2	82669-1

Protection times indicate hours of protection approved for placement on the product label. This approved information is based on the technical information provided by the company on the effectiveness of the product against mosquitoes and/or ticks.

An asterisk (*) indicates that EPA has technical information on the effectiveness of the product against mosquitoes and/or ticks and the company chose not to have a specific time associated with their product.

[†] The product list includes distributor products.

Frequently Asked Questions

Product List - EPA's Insect Repellent Website

1. What information will be contained in the website?

The new EPA website will include an updated webpage on the use and effectiveness of skin-applied insect repellents. This page contains information on how to choose an insect repellent product, sorted product listings, use and safety, and ways to learn more about vector-borne diseases such as Lyme disease and West Nile Virus.

On the insect repellent website, the user will be able to sort the product list by company name, product name, and EPA registration number. Each product will show the active ingredient, the percentage of active ingredient in the formulation, and the hourly protection times from mosquitoes and ticks as claimed by the products.

2. What information will be displayed regarding the hourly protection times?

The website will display protection times approved for placement on the product label. This approved information is based on the technical information provided by the company on the effectiveness of the product against mosquitoes and/or ticks.

In response to comments made on the draft tables sent to registrants in June, EPA has modified the way in which the protection times for products without label-approved protection times will be displayed. An asterisk (*) will be used to indicate that EPA has technical information on the effectiveness of the product against mosquitoes and/or ticks and the company chose not to have a specific time associated with their product.

Revisions to protection times must be made through the label amendment process as discussed in FAQ # 3 below.

3. What process must be followed to revise insect repellent product information that will appear on the website?

All revisions to product names, formulation information, hourly protection times, and other product-specific information must be conducted through the label amendment process. These actions fall under the Pesticide Registration Improvement Renewal Act (PRIA 2).¹

The Agency's regulations (40 CFR 152.46 and PR Notice 98-10²) allow registrants to make certain modifications to their label without Agency approval, provided the changes have no potential to cause unreasonable adverse effects to the environment.

¹ Pesticide Registration Improvement Renewal Act (PRIA 2) Tables - FY 2009/FY 2010 Fee Schedule for Registration Applications

<http://www.epa.gov/pesticides/regulating/fees/tool/category-table.html>

² http://www.epa.gov/opppmsd1/PR_Notices/pr98-10.pdf

Some of these changes can be made simply through "Notification" by submitting the following to the Document Processing Desk (see Chapter 4, Section II, c. of the Label Review Manual)³:

- i. a completed and certified EPA Form 8570-1 (Application for Registration)⁴ marked "Notification," with an explanation, and
- ii. a copy of the label with changes highlighted.

Notifications are generally processed within 30 days. If the "Notification" documents raise a concern with the label reviewer, he or she may require the registrant to submit an application for amendment (40 CFR 152.46).

Depending on the nature of the label amendment, submission of a registration service fee may or may not be required. An amendment changing a primary product name, adding an alternate product name, or changing an alternate product name does not require a fee. An amendment requiring a data review within a regulatory division can range between \$3,444 and \$4,110. For more information, please contact the registration ombudsman, visit the EPA web page on PRIA 2, or see Chapter 4, Section III of the Label Review Manual.

4. What process must be followed to have a product removed from the website?

If an active insect repellent registration has multiple product names, a product name may be removed from the product listing if the registrant follows the notification procedure described in Question #2 to amend the registration.

If an active insect repellent registration only has one product name, that registration must be cancelled to be removed from the website product listing.

5. Will the product list on EPA's insect repellent website include only commercially-available products or all actively EPA-registered insect repellent products?

The product list on the insect repellent website will include all EPA-registered skin-applied insect repellent products, whether or not they are currently sold in the marketplace. EPA does not have a formal process to distinguish between products with active registrations which are available in the marketplace - and those with active registrations, which could be marketed at any time, but which the registrant has decided not to currently distribute.

6. What is a supplemental distributor product?

Section 3(e) of FIFRA allows pesticide registrants to distribute or sell a registered pesticide product under a different name and company instead of or in addition to their own. Such distribution and sale is termed "supplemental distribution" and the product is termed "distributor product." EPA requires the pesticide registrant to submit a Notice of Supplemental Distribution (EPA Form 8570-5)⁵ to the Agency upon entering into an agreement with a second company to distribute the registrant's product under the second company's name and product name. The EPA Form 8570-05 must furnish the following information:

³ <http://www.epa.gov/oppfead1/labeling/lrm/chap-04.htm#IIID>

⁴ <http://www.epa.gov/opprd001/forms/8570-1.pdf>

⁵ <http://www.epa.gov/opprd001/forms/8570-5.pdf>

1. EPA registration number of the product to be distributed.
2. Distributor company number.
3. Name and address of the basic product registrant.
4. Name of the registered product to be distributed.
5. Name to be used on the distributed product.
6. Name and address of the distributor.
7. Signature and title of the distributor and date signed.
8. Signature and title of the basic product registrant and date signed.

Please note that the distributor product must bear the same label claim as the basic product, but may remove a particular claim.

7. Will the product list on the website include all skin-applied insect repellent products with active EPA registrations, or will it exclude the supplemental distributor products?

The insect repellent product listing website will include all active, EPA-registered, skin-applied insect repellent products, including those which are supplemental distributor products.

Supplemental distributor products are indicated with an additional company code following the format of the EPA Registration Number: "Company Code-Product Code-Company Code".

For example, EPA Registration No. 305-29-71410 refers to product registered to WPC Brands, Inc (305-29) that is supplemental packaged and distributed by Degil Safety Products, Inc (company code 71410).

8. Will a supplemental distributor product be removed from the website list if the basic product's registrant and the distributor have dissolved their distribution agreement?

The website's distributor product list will reflect the EPA's database. To request that the distributor status on the Agency's registration database be changed, the core registrant will need to submit one of two notifications of cancelation. The basic product's registrant can stamp or write "Cancel" across the original Notice of Supplemental Distribution of a Registered Pesticide Product (Form 8570-5) and send this form to the address on the form. Alternatively, the basic product registrant can write a memo to the contact address on the form clearly stating that it is no longer under a supplemental distribution agreement for a particular registered product with a distributor company.

9. How often does EPA plan to update the insect repellent product listing website?

This listing will be updated as appropriate to reflect significant changes in information. As of this time, EPA plans to update the product listing website on at least an annual basis, normally between March and April.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

January 8, 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Heather R. Bjornson
Regulatory Assistant to HOMES, L.L.C.
Technology Sciences Group, Inc.
1150 18th St., NW, Suite 1000
Washington, DC 20036

RE: Product Name: Bio-UD-8 Spray
EPA Reg. No: 82669-2
Application for label Notification Dated December 15, 2008 to Make Minor Label Change
Under Directions For Use, Add Optional Label Claim and Add Two Alternate
Brand Names: (1) Bite Blocker BioUD Insect Repellent and (2) Bite Blocker BioUD
Clothing & Gear Insect Repellent

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under Pesticide Registration Notice (PRN) 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at hudson.diana@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

January 8, 2009

2B63

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Heather R. Bjornson
Regulatory Assistant to HOMES, L.L.C.
Technology Sciences Group, Inc.
1150 18th St., NW, Suite 1000
Washington, DC 20036

RE: Product Name: Bio-UD-8 Spray
EPA Reg. No: 82669-2
Application for label Notification Dated December 15, 2008 to Make Minor Label Change
Under Directions For Use, Add Optional Label Claim and Add Two Alternate
Brand Names: (1) Bite Blocker BioUD Insect Repellent and (2) Bite Blocker BioUD
Clothing & Gear Insect Repellent

Dear Ms. Bjornson:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under Pesticide Registration Notice (PRN) 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received and reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Ms. Diana Hudson at (703) 308-8713 or email at HUDSON.DIANA@EPA.GOV.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

35 519
Macf 1/8/10



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82669-1 and 82669-2	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HOMS LLC/ Bite blocker Bio-UD 8 spray and lotion	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) HOMS LLC P.O. Box 724 Clayton Center, Clayton, NC 27520 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>06/03/08</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input checked="" type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container

3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container see attached sheet	5. Location of Label Directions <input type="checkbox"/>
--	---	---

6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____
---	--------------------------------------

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Iain Weatherston	Title Senior Regulatory Consultant	Telephone No. (include Area Code) 623-353-060
--------------------------	---------------------------------------	--

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Senior Regulatory Consultant	6. Date Application Received (Stamped)
4. Typed Name Iain Weatherston	5. Date June 19, 2008	



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input type="checkbox"/>	Amendment
<input checked="" type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82669-2	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BIO-UD-8 SPRAY	PM# BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) HOMS L.L.C P.O. Box 724 Clayton, NC 27520 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/>	Amendment - Explain below.	<input type="checkbox"/>	Final printed labels in response to Agency letter dated _____
<input type="checkbox"/>	Resubmission in response to Agency letter dated _____	<input type="checkbox"/>	"Me Too" Application.
<input checked="" type="checkbox"/>	Notification - Explain below.	<input type="checkbox"/>	Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This notification is to add two alternate brand names to the product's registration/label and is not subject to PRIA.

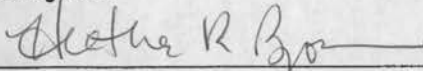
NOTIFICATION

PRIA.
 Date Reviewed: 1-8-09
 Reviewed By: D. Hudson

Section - III

1. Material This Product Will Be Packaged In:				
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No
Certification must submitted		If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt No. per container
2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____				
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> _____
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, Technology Sciences Group, Inc.	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 828-8945
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Assistant to HOMS L.L.C.	
4. Typed Name Heather R. Bjornson	5. Date December 15, 2008	

**WASHINGTON**

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Linda Hollis
 Biopesticide and Pollution Prevention Division
 Office of Pesticide Programs
 Room S-4900, One Potomac Yard
 2777 South Crystal Drive
 Arlington, VA 22202-4501

December 15, 2008

SACRAMENTO

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

RE: HOMS L.L.C.: BIO-UD-8 SPRAY (EPA Reg. No. 82669-2)**Notification per PR Notice 98-10**

Dear Linda:

Technology Sciences Group, on behalf of HOMS L.L.C., is submitting the enclosed notification to add two alternate brand names and make other minor text additions/revisions.

You will find the following in support of this notification:

- 1) Notification application form,
- 2) One copy of the redline label per alternate brand name, and
- 3) One clean copy of the label per alternate brand name.

Please do not hesitate to contact me with any questions at (202) 828-8945 or via e-mail: hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson
 Regulatory Assistant to HOMS L.L.C.

CANADA

275 Slater Street

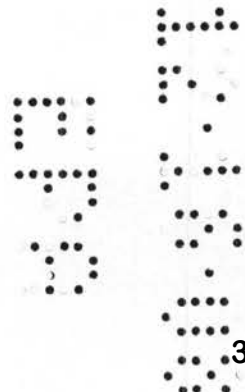
Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

Fax 613 236-3754



NOTIFICATION

Date Reviewed: 1-8-09

Reviewed By: D. Hudson

Front panel

Bite Blocker BioUD Insect Repellent

Repels mosquitoes for up to 4.5 hours

Repels mosquitoes that may carry West Nile Virus for up to 4.5 hours.

Protection for up to 4.5 hours from mosquitoes that may transmit West Nile Virus

Repels ticks and other arthropods

Repels mosquitoes that may transmit West Nile Virus

Repels ticks that may transmit Rocky Mountain Spotted Fever for up to two hours

Repels ticks that may transmit Lyme Disease for up to 2 hours

ACTIVE INGREDIENT

2-Undecanone [CAS# 112-12-9] 7.75%

OTHER INGREDIENTS 92.25%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

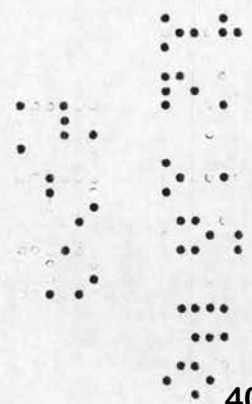
[See back panel for additional precautionary statements and the directions for use]

EPA Reg.No. 82669-2

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

Version 112608



PRECAUTIONARY STATEMENTS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes.
- Remove contact lenses after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9.30 am and 7.30 pm) for emergency treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product.

An adult should apply this product to children under 10 years of age.

Do not allow children to apply this product

General Instructions:

Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 hours. For (extra) (added) protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to hands of young children. For continuous protection against target pests, apply every 4.5 hours or after swimming, toweling or vigorous activity. [Wash treated areas of skin with soap and water after returning indoors].

STORAGE AND DISPOSAL

Storage:	Store in original container in a cool, dry area inaccessible to children
Disposal:	Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.
If partially filled:	Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

Optional Label Claims:

- Can be applied on skin & clothing

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Iain Weatherston, Ph.D.
 Senior Regulatory Consultant
 Technology Sciences Group Inc.
 Arizona: Regulatory Division
 4061 North 156th Drive
 Goodyear, AZ 85338

^{D3}
 JUN 09 2008

Re: Final Printed Label for EPA Registration Number 82669-2
 Your Letter Dated July 29, 2007

Dear Dr. Weatherston:

Your final printed labeling, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, was reviewed and the following changes need to be made:

The brand name "Bite Blocker" is not acceptable as the term "blocker" suggests the product's mode of action is to block the biting of insects. Use of the term would necessitate the submission of additional data demonstrating the blocking effectiveness of the product. PR Notice 98-10 allows the addition of alternate brand names by notification but states that brand names may not be false or misleading. Since repelling is the actual mode of action of the product, this brand name would be considered false or misleading.

This alternate brand name "Bite Blocker" was proposed to EPA via notification on 5/22/07 and this notification was denied by EPA on 6/19/07. EPA has not received another notification or amendment application regarding an alternate brand name since that time. To date, the alternate brand name "Bite Blocker" has not been approved by EPA.

Also, the following corrections need to be made on the current master label (approved 3/15/07):

The claim "Protects against mosquito borne diseases for 4.5 hours" can not be allowed as this claim may be interpreted as the product providing immunity to disease, not repellency against biting insects.

CONCURRENCES

SYMBOL	▶ 7511P							
SURNAME	▶ Fournier							
DATE	▶ 3 Jun 08							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Iain Weatherston, Ph.D.
EPA Reg. No. 82669-2

The claim "Repels ticks and mosquitoes that may transmit Lyme Disease" can not be allowed as mosquitoes do not transmit that disease. The claim is acceptable if "and mosquitoes" is removed.

The proposed claim "block the bite" is not acceptable as it suggests a blocking mode of action, rather than repellency.

Before your next label printing, please revise the master label and final printed label in accordance with the changes directed above. Resubmit the new master label and final printed label prior to shipment of your product.

Failure to make the directed changes will subject your client's registration to cancellation in accordance with FIFRA section 6(e).

If you have any questions concerning this letter, please contact me at (703) 308-8733.

Sincerely,

Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

CONCURRENCES

SYMBOL	▶ 7511P							
SURNAME	▶ Fournier							
DATE	▶ 3 Jun 08							

Material to be added to an e-Jacket

Reg. No 82669-2

1. Placement within the e-Jacket:

- ☒ Default: chronological top
 - ☐ Other: (PDF page number, i.e., "before page 45")
-

2. Is this material:

- ☐ Newly stamped accepted label
- ☐ Notification
- ☒ New CSF
- ☐ Final Printed Label
- ☐ Other:

3. Attach this notice on top of the material. It must be clipped all together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center.

Reviewer's Name Linda Rokert S

Phone: 703-308-0045 Division: BPPD

Date: 4/30/08

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 20 2008

Ms. Heather R. Bjornson
 HOMS L.L.C.
 c/o Technology Sciences Group Inc.
 1150 18th St. N.W.
 Suite 1000
 Washington, DC 20036

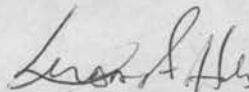
Subject: BIO-UD-8 SPRAY
EPA Reg. No. 82669-2
CSF Amendment (Fast Track) – Resubmission
Application Dated: March 10, 2008
(EPA Submission No. S825971)

The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(5), is acceptable provided that you submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended product constitutes acceptance of these conditions.

If you have any questions, contact Linda Roberts at phone #703-308-0045 or by email at roberts.linda@epa.gov.

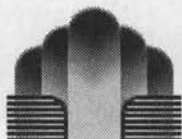
Sincerely,



Linda A. Hollis, Chief
 Biochemical Pesticides Branch
 Biopesticides and Pollution
 Prevention Division (7511P)

CONCURRENCES

SYMBOL	7511P	7511P						
SURNAME	Roberts	Byrne						
DATE	3/26/08	3/26/08						



Nina
Simeonova/DC/USEPA/US
03/24/2008 02:39 PM

To Linda Roberts/DC/USEPA/US@EPA
cc
bcc
Subject S: 825971

The additional information and the revision of the CSF submitted by the registrant/consultant makes the application for formulation amendment of EPA Reg. No. 82669-2 (S: 825971) acceptable.

Nina Simeonova, Chemist
NOWCC SEE Program Enrollee
OPPTS/OPP/BPPD (7511P)
PY1, S-8712
Phone: 703-308-0291
Fax: 703-308-7026
Email: simeonova.nina@epa.gov

Receipt for Section 3

S: 825971 Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3 Fee For Service: ☐ Yes ☒ No

Application Type: Amendment Billable: ☐ Yes ☒ No

Company: 82669 HOMS, LLC V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82669-2 Product Name: BIO-UD-8 SPRAY

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 10-Mar-2008 OPP Rec'd Date: 11-Mar-2008

Front End Date: 11-Mar-2008 Risk Manager Send Date: 12-Mar-2008

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content:

Print Letter

Enter More Information

Tracking

EPA-PRISM Main - Co... 3:17 PM

Resubmission: Response
to a letter dated 3/6/08.
Please forward to Andy.
MAR 18 2008
Thanks.
Dress

AIO-Andy
MAR 18 2008
sdh

82669-2

03/15/2007

1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

82669-2

Date of Issuance:

3/15/07

NOTICE OF PESTICIDE:

☒ Registration ☐ Re-registration
(under FIFRA, as amended)

Term of
Issuance:

Unconditional

Name of Pesticide Product:

BIO-UD-8 SPRAY

Name and Address of Registrant (include ZIP Code):

HOMS L.L.C
PO BOX 724
Clayton Center
Clayton, NC 27520

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c) (5) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 82669-2"
3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division

Date:

3/15/07

CONCURRENCES

SYMBOL	EPA Form 8570-6	7511P	7511P	7511P				
SURNAME		WILKINS	COLE	HOLLIS				
DATE		3/12/07	3/15/07	3/15/07				

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

82669-2

03/15/2007

14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

82669-2

Date of Issuance:

3/15/07

NOTICE OF PESTICIDE:

☒ Registration ☐ Re-registration
(under FIFRA, as amended)

Term of
Issuance:

Unconditional

Name of Pesticide Product:

BIO-UD-8 SPRAY

Name and Address of Registrant (include ZIP Code):

HOMS L.L.C
PO BOX 724
Clayton Center
Clayton, NC 27520

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c) (5) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 82669-2"
3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division

Date:

3/15/07

CONCURRENCES

SYMBOL	7511P	7511P	7511P				
SURNAME	R. Wilkins	COLE	HOLLIS				
DATE	3/12/07	3/15/07	3/15/07				

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Front panel

BIO-UD-8 Spray

Repels mosquitoes for 4.5 hours

Protects against mosquito borne diseases
for 4.5 hours

Block the Bite

Repels mosquitoes that may transmit
West Nile VirusRepels ticks that may transmit
Lyme Disease for up to 2 hoursRepels mosquitoes that may carry West Nile Virus for
4.5 hours.Protection for 4.5 hours from
mosquitoes that may transmit West Nile Virus

Repels ticks and other arthropods

Repels ticks that may transmit Rocky
Mountain Spotted FeverRepels ticks and mosquitoes that
may transmit Lyme Disease**ACTIVE INGREDIENT**

2-Undecanone [CAS# 112-12-9]

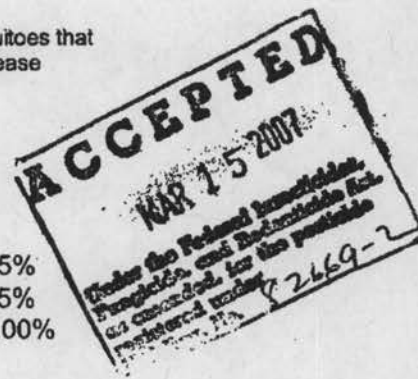
7.75%

OTHER INGREDIENTS

92.25%

TOTAL

100.00%

**KEEP OUT OF REACH OF CHILDREN****CAUTION**

[See back panel for additional precautionary statements and the directions for use]

EPA Registration Number 82669-E

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

Iteration 4 [031507]

PRECAUTIONARY STATEMENTS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID**IF SWALLOWED:**

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9.30 am and 7.30 pm) for emergency treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product.

An adult should apply this product to children under 10 years of age.

Do not allow children to apply this product

General Instructions:

Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 hours. For added protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 4.5 hours or after swimming, toweling or vigorous activity. [Wash treated areas of skin with soap and water after returning indoors].

STORAGE AND DISPOSAL

Storage:	Store in original container in a cool, dry area inaccessible to children
Disposal:	Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.
If partially filled:	Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

82669-2

Date of Issuance:

3/15/07

NOTICE OF PESTICIDE:

☒ Registration ☐ Re-registration
(under FIFRA as amended)

Term of
Issuance:

Unconditional

Name of Pesticide Product:

BIO-UD-8 SPRAY

Name and Address of Registrant (include ZIP Code):

HOMS L.L.C.
PO BOX 724
Clayton Center
Clayton, NC

Note: Changes in labeling or other information in substance from that accepted in connection with this registration must be submitted to the Administrator, Office of Pesticide Programs and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this registration, please refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration may not be construed as an endorsement or recommendation of this product by the Agency. In order to protect the public interest, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide under this Act. The acceptance of any name in connection with the registration of a product under this Act is not intended to give the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c) (5) provided you:

1. Submit all data required for registration/ reregistration of your product under FIFRA section 4 when the Agency requires all registrants of similar products to submit data.
2. Notify the Agency of any change before you release the product for shipment: Revise the EPA Registration Number to reflect the change. Reg. No. 82669-2
3. Submit three copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your registration of this product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of:

Date:

3/15/07

Jan 11
EPA
Pesticide

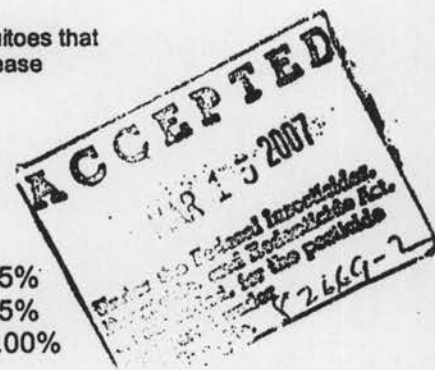
EPA

BIO-UD-8 Spray

Repels mosquitoes for 4.5 hours	Repels mosquitoes that may carry West Nile Virus for 4.5 hours.
Protection from mosquito borne diseases	Protection for 4.5 hours from mosquitoes that may transmit West Nile Virus
Repels ticks and other arthropods	Repels ticks and other arthropods
Repels ticks that may transmit	Repels ticks that may transmit Rocky Mountain Spotted Fever
may transmit up to 2 hours	Repels ticks and mosquitoes that may transmit Lyme Disease

INGREDIENT

2-Undecanone [CAS# 112-12-9]	7.75%
INGREDIENTS	92.25%
TOTAL	100.00%



KEEP OUT OF REACH OF CHILDREN

CAUTION!

For additional precautionary statements and the directions for use]

EPA F 82669-E

EPA Establishment Number XXXXX-XX-XX

Net Contents: 4.0 oz 6.7 oz



PRECAUTIONARY STATEMENTS

Harmful
to
aquatic
life
if
released
into
the
environment.
Do
not
use
near
open
water.
Do
not
contaminate
water.
Do
not
use
near
open
water.
Do
not
contaminate
water.

Causes moderate eye irritation. Avoid contact with eyes. Wash with water after handling and before eating, drinking, chewing gum, or

FIRST AID

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have
label
with
you
when
calling
a
poison
control
center
or
doctor
or
also
contact
the
National
Pesticide
Information
Center
at
1-800-
858-7373
(9 am and
7:30 pm)
for
emergency
treatment
advice.

Have label with you when calling a poison control center or doctor or also contact the National Pesticide Information Center at 1-800-858-7373 (9 am and 7:30 pm) for emergency treatment advice.

DIRECTIONS FOR USE

Do not use this product in a manner inconsistent with the labeling.

Read all directions before using this product.

Do not apply this product to children under 10 years of age. Do not allow children to handle this product.

Use:

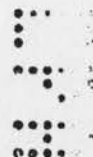
For use: This bottle is designed to be used upside down. For best results spray for added wetting action apply to clothing. Do not apply to lips or keep away from the mouth of young children. For continuous protection against mosquitoes, apply 4-5 hours after swimming, toweling or vigorous activity. Wash hands after use (do not eat or drink after re-entering indoors).

STORAGE AND DISPOSAL

Store in original container in a cool, dry area inaccessible to children. Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.

- 1: 2. Call your local waste agency or 1-800-CLEANUP for disposal instructions. Do not place unused product down any indoor or outdoor drain.

Call 1-800-6721 (between 9 am and 5 pm Eastern time)
or thomson.com

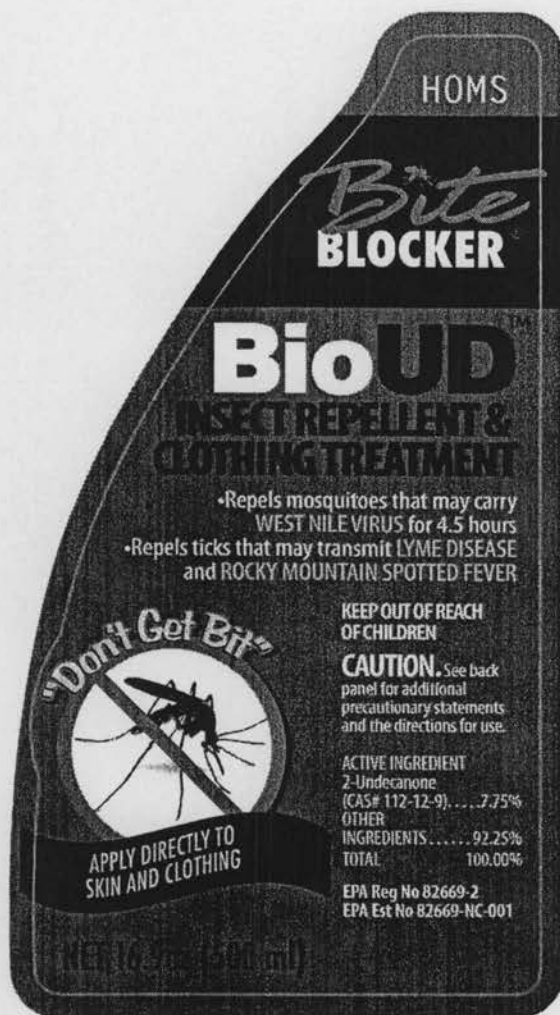


DATE EXPIRATION SHEET.

[illegible]

STORAGE AND DISPOSAL: Store in original container. Do not use for food, feed, or other purposes. Wash and sanitize areas of skin with soap and water after use. Do not use in a cool, dry area inaccessible to children. Use the product according to label directions. For recycling, if available, call 1-800-451-1111 or offer for recycling if available. For disposal: Call your local solid waste authority for disposal instructions. Never place unused product in drains, sewers, or comments. Call 1-888-258-2828 for contact HOMS at CustomerService@homs.com.

PRECAUTIONS:
Harmful if swallowed.
Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.
FIRST AID: IF SWALLOWED: Immediately go for treatment advice. Have person call a poison control center or doctor.
IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing eye. Get medical attention right away. Hold eye open and rinse with water for 15 - 20 minutes. Have person call a poison control center or doctor or go for treatment. You may also contact the National Poison Information Center at 1-800-557-2728 (between 9:30 am and 5:00 pm) for emergency treatment advice.
DIRECTIONS FOR USE: Use as a disinfectant of Federal disinfectant. Do not use this product in a manner inconsistent with labeling. Read all directions before using this product. An adult should apply this product to children under 10 years of age. Do not allow children to apply this product to themselves. Shake well before using. Spray up and down, for best results spray every 4.5 hours or after swimming. Do not apply to the hands of young children. For use against target organisms, apply every 4.5 hours or after swimming. Do not use against target organisms.



APPLY DIRECTLY TO SKIN AND CLOTHING

PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. **FIRST AID: IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person. **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. **HOT LINE NUMBER:** Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9:30 am and 7:30 pm) for emergency treatment advice. **DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all directions before using this product. An adult should apply this product to children under 10 years of age. Do not allow children to apply this product. **GENERAL INSTRUCTIONS:** Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 hours. For added protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 4.5 hours or after swimming, toweling or vigorous activity. (Wash treated areas of skin with soap and water after returning indoors).

STORAGE AND DISPOSAL **STORAGE:** Store in original container in a cool, dry area inaccessible to children. **DISPOSAL:** Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container. **IF PARTIALLY FILLED:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain. Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com.

HOMS, LLC P.O. BOX 724,
CLAYTON, NC 27520





APPLY DIRECTLY TO SKIN AND CLOTHING

PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. **FIRST AID: IF SWALLOWED:**

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person. **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. **HOT LINE NUMBER:** Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9:30 am and 7:30 pm) for emergency treatment advice.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all directions before using this product. An adult should apply this product to children under 10 years of age. Do not allow children to apply this product. **GENERAL INSTRUCTIONS:** Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 hours. For added protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 4.5 hours or after swimming, towel drying or vigorous activity. (Wash treated areas of skin with soap and water after returning indoors).

STORAGE AND DISPOSAL

STORAGE: Store in original container in a cool, dry area inaccessible to children. **DISPOSAL:** Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container. **IF PARTIALLY FILLED:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain. Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com.

HOMS, LLC PO. BOX 724,
CLAYTON, NC 27520



MATERIAL TO BE ADDED TO JACKET

REG #

82669-2

Description:

BIOAD-8 Spray

CSF Amendment -

a minor formulation

check all that apply	
<input type="checkbox"/>	new stamped accepted label
<input checked="" type="checkbox"/>	new CSF
<input type="checkbox"/>	notification

Send to CSC

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's

Name:

Linda Roberts

Date:

3/10/08

Phone:

703-308-0045

Division:

BPAD



WASHINGTON

1150 18th Street, N.W.
Suite 1000
Washington, D.C. 20036
Telephone 202 223-4392
Fax 202 872-0745

Linda Hollis
Biopesticide and Pollution Prevention Division
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

March 10, 2008

RE: HOMES L.L.C.: BIO-UD-8 SPRAY (EPA Reg. No. 82669-2)

Response to EPA letter dated March 6, 2008

SACRAMENTO

712 Fifth Street
Suite A
Davis, CA 95616
Telephone 530 757-1298
Fax 530 757-1299

Dear Linda:

Technology Sciences Group, on behalf of HOMES L.L.C., is submitting the enclosed response to the EPA letter referenced above. Included in this submission are the revised basic and alternate formulation CSFs for amending this registration. These changes in the basic and alternate formulations in no way invalidate the currently registered product specific properties.

You will find the following in support of this formulation amendment:

- 1) EPA application form (8570-1),
- 2) Two copies of both the proposed basic and alternate formulation CSFs,
- 3) One copy of the basic and alternate formulation CSFs currently on file, and
- 4) The MSDS for the inert ingredient being added to the formulations.

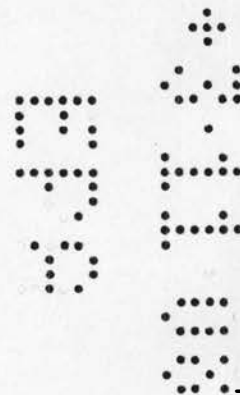
CANADA

275 Slater Street
Suite 900
Ottawa, Ontario
K1P 5H9
Telephone 613 247-6285
Fax 613 236-3754

Please do not hesitate to contact me with any questions at (202) 828-8945 or via e-mail: hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson
Regulatory Assistant to HOMES L.L.C.





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82669-2	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BIO-UD-8 SPRAY	PM# BPPD/Biochemical Pesticides	
5. Name and Address of Applicant (Include ZIP Code) HOMS L.L.C P.O. Box 724 Clayton, NC 27520 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>3/6/2008</u>	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This submission is a minor formulation amendment per PR Notice 98-10 and is not subject to PRIA.

EPA Submission No. 822431

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Heather R. Bjornson, Technology Sciences Group, Inc.	Title Regulatory Assistant	Telephone No. (Include Area Code) (202) 828-8945
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Assistant to HOMS L.L.C	
4. Typed Name Heather R. Bjornson	5. Date March 10, 2008	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

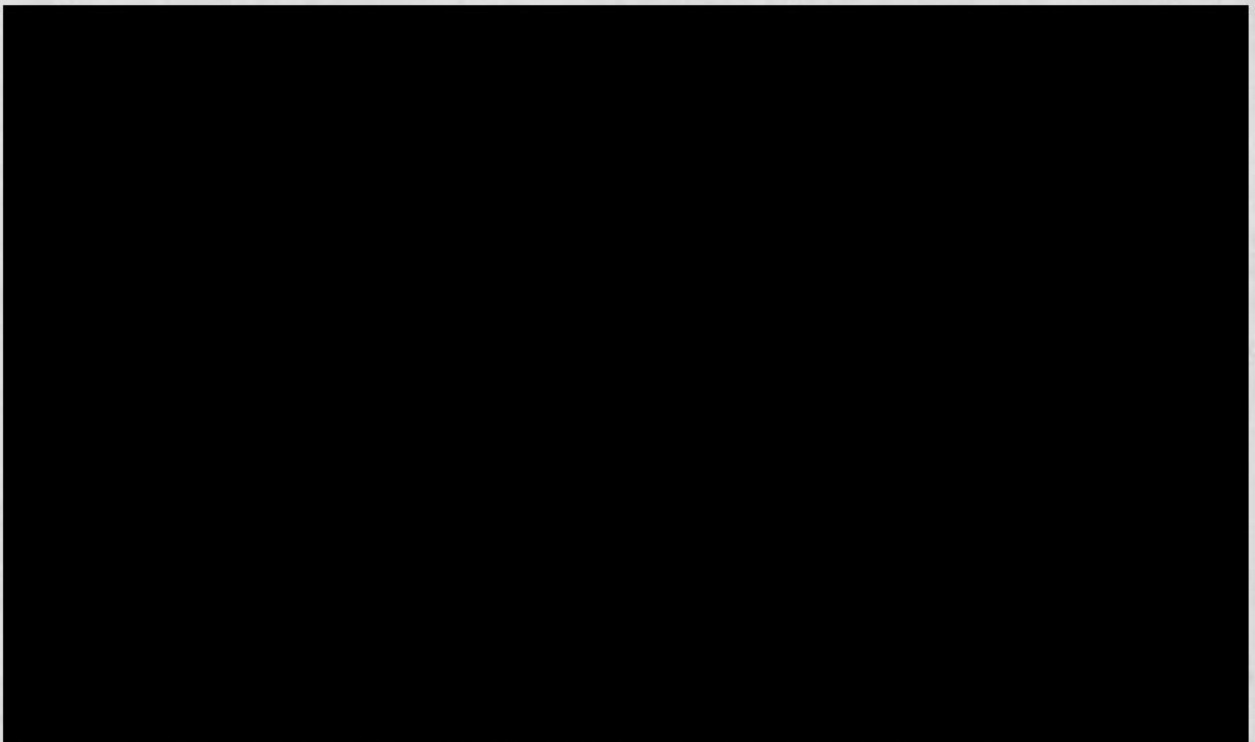
MAR - 6 2008

Ms. Heather R. Bjornson
HOMS L.L.C.
c/o Technology Sciences Group Inc.
1150 18th St. N.W.
Suite 1000
Washington, DC 20036

Subject: BIO-UD-8 SPRAY
EPA Reg. No. 82669-2
CSF Amendment (Fast Track) - Minor Formulation Amendment
Application Dated: January 8, 2007
(EPA Submission No. 822431)

Dear Ms. Bjornson:

This application referred to above, submitted in connection with registration under FIFRA section 3 (c) (5) cannot be approved until the following issues are resolved:



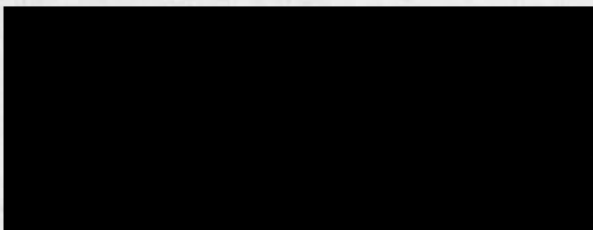
Inert ingredient information may be entitled to confidential treatment

CONCURRENCES								
SYMBOL	▶ 17511P	7511P						
SURNAME	▶ Roberts	Byersland						
DATE	▶ 3/5/08	3/5/07						

EPA Form 1320-1A (1/90) Printed on Recycled Paper

OFFICIAL FILE COPY

80



6. It is necessary to submit a statement that the changes in the basic and the alternate formulations will not invalidate the currently registered product specific properties.

Your application will be kept active for a period of 75 days to give you an opportunity to correct the listed deficiencies. If you find that you need more time to complete the requirements, you should request an extension and commit yourself to satisfy the deficiencies within a reasonable stated period of time. If this procedure is not followed, the Agency may administratively withdraw your application from further consideration without further notice to you in accordance with the policy established by PR Notice 75-4 of August 27, 1975. After that, you will have to submit a complete new application should you wish to pursue the amendment.

Please contact Ms. Linda Roberts at 703-308-0045 or by email at Roberts.Linda@epa.gov, if you have any questions concerning this letter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda A. Hollis".

Linda A. Hollis
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division
(7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

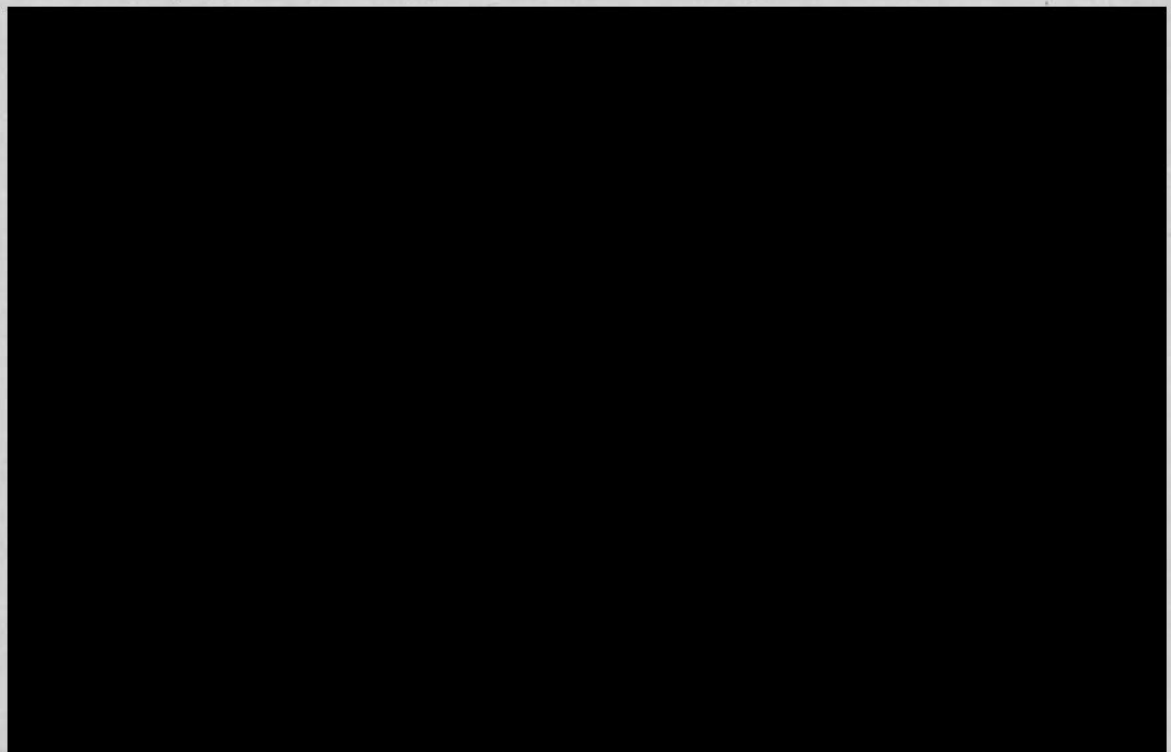
MAR - 6 2008

Ms. Heather R. Bjornson
HOMS L.L.C.
c/o Technology Sciences Group Inc.
1150 18th St. N.W.
Suite 1000
Washington, DC 20036

Subject: BIO-UD-8 SPRAY
EPA Reg. No. 82669-2
CSF Amendment (Fast Track) - Minor Formulation Amendment
Application Dated: January 8, 2007
(EPA Submission No. 822431)

Dear Ms. Bjornson:

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Inert ingredient information may be entitled to confidential treatment

CONCURRENCES							
SYMBOL	▶ 7511P	7511P					
SURNAME	▶ Roberts	Boydland					
DATE	▶ 3/5/08	3/5/08					



6. It is necessary to submit a statement that the changes in the basic and the alternate formulations will not invalidate the currently registered product specific properties.

Your application will be kept active for a period of 75 days to give you an opportunity to correct the listed deficiencies. If you find that you need more time to complete the requirements, you should request an extension and commit yourself to satisfy the deficiencies within a reasonable stated period of time. If this procedure is not followed, the Agency may administratively withdraw your application from further consideration without further notice to you in accordance with the policy established by PR Notice 75-4 of August 27, 1975. After that, you will have to submit a complete new application should you wish to pursue the amendment.

Please contact Ms. Linda Roberts at 703-308-0045 or by email at Roberts.Linda@epa.gov, if you have any questions concerning this letter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Linda A. Hollis".

Linda A. Hollis
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division
(7511P)

Fast Track Team ACTION SHEET

File Symbol/Number	RAL	SUBMISSION Number	Action Code
82669-2	Linda Roberts	822431	300
Date Assigned	Notes CSF Amendment to add an inserting redissent		
1/22/08			
Due Date (Letter Done!!!) <small>Please inform Chris Pfeifer if you cannot have a letter done by the Due Date.</small>			
3/6/08			
General Directions (See Chris Pfeifer at any time for guidance or relevant forms.)			
1. Make sure your name is entered in OPPIN as the reviewer of record.	5. Prepare an approval / deficiency package. Use a letter template w/ boilerplate. Capture the nature of the request for amendment in the letter's subject heading. Place 2 concurrence copies and 1 letterhead copy in the package. Include correspondence, checklists, internal reviews, notes-to-file, etc... in concurrence package.	7. Close submission in OPPIN. If it's a deficiency letter, set a tickler date 75 days out so that you can withdraw the application at that time.	
2. Review the jacket for relevant notes-to-file or conditions of registration.		8. Stamp letters with date. Stamp approved labels. Send letterhead copy to registrant. (Include a stamped label and an A-79 with approval letters.) Put submission # and response code on concurrence copies.	
3. Do a label and/or CSF review. Use the relevant checklists. (User share or Chris Pfeifer)		9. Put 1 concurrence copy in the chron file.	
4. Make a determination if deficiencies can be fixed by the due date without a formal letter. Have a deficiency letter ready by 75 day date in the event the registrant fails to meet this 75 day deadline.		10. Put stamped labels in label file.	
		11. Add all relevant documents go into e-jacket. (Use latest e-jacket cover sheet from Intranet.) Route new labels to contractor (formerly SIG) for scanning.	

Action Sheet 2007



Russell Jones/DC/USEPA/US
03/04/2008 01:50 PM

To: Nina Simeonova/DC/USEPA/US@EPA
cc: Andrew Bryceland/DC/USEPA/US@EPA, Linda
Roberts/DC/USEPA/US@EPA
bcc:
Subject: Re: The [REDACTED] in UD-8 Spray, EPA 82669-2

Nina:

The way the memo is written is a bit confusing, but.....

The surfactant [REDACTED] is contained within OPPIN. That is also the inert that is listed on the CSF. Since that agrees with what is in OPPIN, it does not matter whether its components are in OPPIN or not. The inert mixture IS IN OPPIN. That is all that matters at this point.

You are going way to deep in the inert review for this product. No new information needs to added to OPPIN

Russ

Nina Simeonova/DC/USEPA/US



Nina
Simeonova/DC/USEPA/US
03/04/2008 01:40 PM

To: Andrew Bryceland/DC/USEPA/US@EPA, Russell
Jones/DC/USEPA/US@EPA
cc: Linda Roberts/DC/USEPA/US@EPA
Subject: The [REDACTED] in UD-8 Spray, EPA 82669-2

This is in response to the suggestion to delete the paragraph in my memo about the [REDACTED] ingredient

While preparing the memo I have found in OPPIN Database that [REDACTED] is registered with EPA and is identified as a [REDACTED] each further identified by CASRN and PC Code as follows:

[REDACTED]

The registrant wants to use in the amended formulation [REDACTED] (See the attached MSDS). It is in the MSDS, Section 2, that [REDACTED]

[REDACTED]

There is a mistake in the trade name of the [REDACTED] in the draft CSF [REDACTED] but it will be cleared if the information is revised according to the attached MSDS.

So I did not find a mistake in the paragraph in question and do not see the reason for deletion. If the correction is made as recommended it will identify the new inert ingredient more precisely and in

compliance with the MSDS as a [REDACTED]

Probably it will be easy to enter [REDACTED] in OPPIN because of the close similarity with [REDACTED]
[REDACTED] only with the information from the MSDS, the composition is revealed. Alga Debesai
(RD, Inerts) should know.

Nina Simeonova, Chemist
NOWCC SEE Program Enrollee
OPPTS/OPP/BPPD (7511P)
PY1, S-8712
Phone: 703-308-0291
Fax: 703-308-7026
Email: simeonova.nina@epa.gov

Linda Roberts/DC/USEPA/US
03/03/2008 01:52 PM

To "Heather Bjornson" <HBjornson@TSGUSA.COM>
cc
bcc Andrew Bryceland/DC/USEPA/US@EPA
Subject RE: Review Status for EPA Registration 82669-2 Minor
Formulation Amendment Submission

Heather,

In response to your inquiry, the CSF amendment is still in review. A written response will be sent to you shortly.

Best Regards,

Linda Roberts
NOWCC Enrollee
Data Management
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
roberts.linda@epa.gov
703-308-0045 (phone)
703-308-7026 (fax)
"Heather Bjornson" <HBjornson@TSGUSA.COM>



"Heather Bjornson"
<HBjornson@TSGUSA.COM>
>
02/27/2008 05:25 PM

To Linda Roberts/DC/USEPA/US@EPA
cc
Subject RE: Review Status for EPA Registration 82669-2 Minor
Formulation Amendment Submission

Linda -
Any news on the minor formulation amendment for EPA Reg. No. 82669-2 for HOMS LLC? It has been more than 45 days.

Regards,
Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington DC 20036
Tel.: (202) 828-8945
Fax: (202) 872-0745

-----Original Message-----

From: Hobgood.Sherada@epamail.epa.gov [mailto:Hobgood.Sherada@epamail.epa.gov]
Sent: Thursday, February 07, 2008 3:33 PM
To: Heather Bjornson
Cc: Roberts.Linda@epamail.epa.gov
Subject: Re: Review Status for EPA Registration 82669-2 Minor Formulation
Amendment Submission

Hi...Heather,

This is a follow-up response to your e-mail inquiry concerning the review status of EPA Registration 82669-2 that I neglected to mention in my earlier e-mail response. If you don't already know by now, the subject registration is assigned to Linda Roberts (703/308-0045) in the BioPesticides Division.

Sherada Hobgood
Minor Formulations Review Coordinator
Registration Division, OPP
703/308-8893 (office)
703/305-6920 (fax)

"Heather
Bjornson"
<HBjornson@TSGUS
A.COM>

To
Sherada Hobgood/DC/USEPA/US@EPA
cc

02/04/2008 04:55
PM

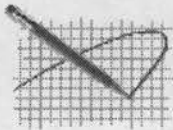
Subject
Minor Formulation Amendments

Sherada -

I am writing to check on the status of two minor formulation amendments. They are for EPA Reg. Nos. 82669-2, submitted Dec 7, 2007; and 69061-12, submitted Dec 10, 2007.

I appreciate any information that you can provide.

Regards,
Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington DC 20036
Tel.: (202) 828-8945
Fax: (202) 872-0745



Andrew
Bryceland/DC/USEPA/US
03/03/2008 11:48 AM

To: Linda Roberts/DC/USEPA/US@EPA
cc
bcc
Subject: Re: Fw: Review Status for EPA Registration 82669-2 Minor
Formulation Amendment Submission

Linda,

I am not in the office today, but I will be in tomorrow. I will also call you after I send this. Basically, tell the registrant the the CSF amendment application is still in review, and she will get a written response from the Agency.

I think this is the submission that we spoke real briefly about last week so I believe Nina did her review. Can you please write up the CSF amendment deficiency letter using Nina's review. If there are deficiencies in Nina's review that are not clear to you in terms of what the registrant needs to do to fix the problem, then speak to Nina and ask her what the registrant needs to do to fix the problem. She may need to revise her science review memo.

I will be in tomorrow so we can speak further about this if we still need to.

Andy

-----Linda Roberts/DC/USEPA/US wrote: -----

To: Andrew Bryceland/DC/USEPA/US@EPA
From: Linda Roberts/DC/USEPA/US
Date: 03/03/2008 10:38AM
Subject: Fw: Review Status for EPA Registration 82669-2 Minor Formulation Amendment Submission

Andy,

Heather is asking about this amendment. What can I tell her? 3/6/08 is due date for this amendment. Please let me know.

Thanks.

Linda Roberts
NOWCC Enrollee
Data Management
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
roberts.linda@epa.gov
703-308-0045 (phone)
703-308-7026 (fax)

----- Forwarded by Linda Roberts/DC/USEPA/US on 03/03/2008 10:36 AM -----

"Heather
Bjornson"
<HBjornson@TSG
USA.COM>

To: Linda Roberts/DC/USEPA/US@EPA
cc

02/27/2008 05:25
PM

Subject: RE: Review Status for EPA Registration 82669-2 Minor
Formulation Amendment Submission



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFF

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 15, 2008

SUBJECT: Fast Track Amendments of the basic and alternate formulation of the product Bio-UD-8 Spray, EPA Reg. No. 82669-2 containing as its active ingredient 7.75 % 2-Undecanone

Decision Number:	38676
Submission Number:	822431
Chemical Class:	Biochemical
PC Code:	044102
CAS Number:	112-12-9
Active Ingredient Tolerance Exemptions:	Not applicable, non-food use

FROM: Nina Simeonova, Chemist, NOWCC - SEE Enrollee
Biopesticides & Pollution Prevention Division (7511P)

TO: Linda Roberts, RAL, NOWCC - SEE Enrollee
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

On behalf of HOMS L.L.C. TSG Inc. requests amendment of the currently registered basic and alternate formulation of Bio-UD-8 Spray, EPA Reg. No. 82669-2. The product is a mosquito repellent spray containing 7.75 % 2-Undecanone (PC Code 044102, CASRN 112-12-9) in

The following changes, one and the same for the currently registered basic and alternate CSFs dated 12/04/2005, are requested:

Inert ingredient information may be entitled to confidential treatment

[REDACTED]

In support of the request the applicant submitted draft amended basic and alternate CSFs dated 12/07/2007 and MSDS for the new inert ingredient [REDACTED]

RECOMMENDATIONS AND CONCLUSIONS

The application for formulation amendment is unacceptable, but upgradeable after the resolution of the following deficiencies:

- There is inconsistency in the identification of the new inert ingredient in the MSDS and on the CSFs. [REDACTED]
- [REDACTED]
- It is necessary to submit a statement that the changes in the basic and the alternate formulations will not invalidate the currently registered product specific properties.

cc: N. Simeonova, L.Roberts, BPPD Chron File.
N. Simeonova, FT, PY-S. 2/20/08.



Andrew
Bryceland/DC/USEPA/US
01/22/2008 02:50 PM

To Linda Roberts/DC/USEPA/US,
cc
bcc
Subject Fast Track CSF amendment on your shelf for 82669-2

Linda,

The attached is an amendment to add an inert ingredient to the basic and alternate formulations. Please have Nina review the CSF and determine the acceptability of the amendment. If the amendment is acceptable please write up the acceptability letter for my concurrence. If the amendment is not, please see me and we will then determine how to proceed. The due date in March 6, 2008. See below for more information.

Andy

82669-2	Bio-ud-8 spray	Linda Roberts/Nin a	Decis#: 388676	Received and transferred the CSF amendm on 1/22/08. Due date is 3/6/08.
HOMS, LLC			Subm#: 822431	
			Code: 300	

Receipt for Section 3

S: 822431 Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3 Fee For Service: ☒ Yes ☐ No

Application Type: Miscellaneous Receipt *Amend.* Billable: ☒ Yes ☐ No

Company: 82669 HOMES, LLC V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82669-2 Product Name: BIO-UD-8 SPRAY

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 08-Jan-2007 *id* OPP Rec'd Date: 07-Dec-2007 *id*

Front End Date: 07-Dec-2007 *id* Risk Manager Send Date: 09-Jan-2008 *id*

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description: MINOR FORMULATION AMENDS

JAN 1 0 2008

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content

Print Letter

Enter More Information

Tracking

*Fast track
Team - [Signature]
1/16/08
JAN 1 6 2008*

345

*ATD-Andy
JAN 2 2 2008
[Signature]*

91

7505-P

**WASHINGTON**

1150 18th Street, N.W.

Suite 1000

Washington, D.C. 20036

Telephone 202 223-4392

Fax 202 872-0745

Sherada Hobgood

~~Minor Formulation Review Coordinator~~~~Registration Support Branch~~

Office of Pesticide Programs

Room S-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

December 7, 2007

BPPD

RE: HOMS L.L.C.: BIO-UD-8 SPRAY (EPA Reg. No. 82669-2)**Minor formulation amendments per PR Notice 98-10****SACRAMENTO**

712 Fifth Street

Suite A

Davis, CA 95616

Telephone 530 757-1298

Fax 530 757-1299

Dear Sherada Hobgood:

Technology Sciences Group, on behalf of HOMS L.L.C., is submitting the enclosed minor formulation amendments for the basic and alternate formulation of the above referenced product.

You will find the following in support of this formulation amendment:

- 1) EPA application form (8570-1),
- 2) Two copies of both the proposed basic and alternate formulation CSFs,
- 3) One copy of the basic and alternate formulation CSFs currently on file, and
- 4) The MSDS for the inert ingredient being added to the formulations.

CANADA

275 Slater Street

Suite 900

Ottawa, Ontario

K1P 5H9

Telephone 613 247-6285

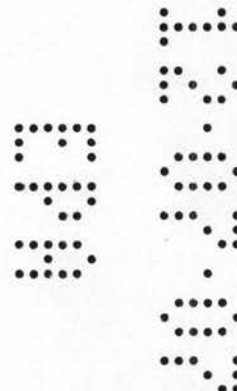
Fax 613 236-3754

Please do not hesitate to contact me with any questions at (202) 828-8945 or via e-mail: hbjornson@tsgusa.com.

Sincerely,

Heather R. Bjornson

Regulatory Assistant to HOMS L.L.C.





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
82669-2

2. EPA Product Manager
Linda Hollis

3. Proposed Classification
☒ None ☐ Restricted

4. Company/Product (Name)
BIO-UD-8 SPRAY

PM#
BPPD/Biochemical Pesticides

5. Name and Address of Applicant (Include ZIP Code)

HOMS L.L.C
P.O. Box 724
Clayton, NC 27520

☐ Check if this is a new address

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☒ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☐ Final printed labels in response to
Agency letter dated _____

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This submission is a minor formulation amendment per PR Notice 98-10 and is not subject to PRIA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes
☐ No

Unit Packaging

☐ Yes
☐ No

Water Soluble Packaging

☐ Yes
☐ No

2. Type of Container

☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify) _____

**Certification must
be submitted**

If "Yes"
Unit Packaging wgt.

No. per
container

If "Yes"
Package wgt

No. per
container

3. Location of Net Contents Information

☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐

6. Manner in Which Label is Affixed to Product

☐ Lithograph
☐ Paper glued
☐ Stenciled

☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name

Heather R. Bjornson, Technology Sciences Group, Inc.

Title

Regulatory Assistant

Telephone No. (Include Area Code)

(202) 828-8945

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

Heather R. Bjornson

3. Title

Regulatory Assistant to HOMS L.L.C

4. Typed Name

Heather R. Bjornson

5. Date

December 7, 2007

6. Date Application
Received
(Stamped)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 02 2007

HOMS, Inc.
c/o Iain Weatherston, Ph.D
P.O. Box 724
Clayton Center, Clayton NC 27520

Subject: Product Name: Bite Blocker BioUD- Spray
EPA Reg. No: 82669-2
Application for label Notification dated June 20, 2007: to add brad name
and verbiage change.

Dear Dr. Weatherston:

The Biopesticides and Pollution Prevention Division is in receipt of your application for Notification under 98-10 dated above. A preliminary screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested falls within the scope of PRN 98-10. Our records have been duly noted, and the label submitted with this application has been stamped "Notification, received, but not reviewed" and will be placed accordingly in our records.

Questions concerning this action should be directed to Mr. Raderrio Wilkins at (703) 308-1259 or email at wilkins.raderrio@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 82669-2

Send to SIG: check box ☒

This material is:

- ☐ New stamped-accepted label
- ☐ New CSF
- ☐ Notification
- ☐ Final Printed Label

☒ Other: Copy of original applicant that should have been put in the packet prior to being sent to BPPD

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be **NO STAPLES** in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: _____

Phone: _____ Division: _____

Date: _____

pt for Section 3

S: 814363 Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3 Fee For Service: ☒ Yes ☐ No

Application Type: Miscellaneous Receipt Billable: ☒ Yes ☐ No

Company: 82669 HOMS, LLC V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82669-1 Product Name: BIO-UD-8 LOTION

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 30-Jul-2007 OPP Rec'd Date: 30-Jul-2007

Front End Date: 30-Jul-2007 Risk Manager Send Date: 01-Aug-2007

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description: final printed labels.

AUG 01 2007

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content:

Print Letter

Enter More Information

Tracking

art EPA-PRISM Main - Co... 6:13 PM

ETT
400

AUG 2 2007

TP

AIO-Chris CAROLE
AUG 3 2007
sdh

AUG 14 2007
CP

Raderrio
Wilkins/DC/USEPA/US
07/12/2007 10:54 AM

To Linda Hollis/DC/USEPA/US@EPA
cc Andrew Bryceland/DC/USEPA/US@EPA,
cole.leonard@epa.gov
bcc
Subject Re: Fw: HOMS products 82669-1 and 86992-2

Linda,

Here is a summary of events surrounding the products referenced above:

1) Labeling: The original stamp label was approved under the name, "BLOD Lotion and Spray". The registrant applied via notification (May 22, 2007) for an Alternate brand name under "Block Bite etc." which was denied on June 19, 2007. The efficacy data submitted does not support an 8 hour protection, instead it supported a 4.5 hour repellency for Mosquitoes and 2 hours for Ticks (HOMS is attempting to omit the required protection time interval from the label). The bottom line, Homs was selling their product with graphics and labeling requested via notification without the Agency's consent or approval.

2) E-mails: The last conversation I had with Iain was on Friday, June 22nd whereby he was instructed to resubmit his application with the necessary corrections and the assigned RAL would contact him when they receive his application (as noted below in his e-mails, never inquired into the status of his submission).

Raderrio

----- Original Message -----

From: [jazkatz](#)
To: Wilkins.Raderrio@epamail.epa.gov
Cc: [Allen](#)
Sent: Tuesday, June 28, 2007 12:37 PM

Raderrio:

I am following up on Tuesday e-mail (see below) since every day counts and if these products do not get into the channels of trade then their future is in jeopardy. I realize as you said when we spoke last that the EPA is not responsible for the financial solvency of companies however it will alleviate the HOMS situation if these products can get to the market place by next week.

We are fast approaching the point of no return to be able to market the products this year and I would rather not put the client in jeopardy by risking the printing, submission and use of the labels submitted on June 21, 2007.

Regards,
Iain

----- Original Message -----

From: [jazkatz](#)
To: Wilkins.Raderrio@epamail.epa.gov
Cc: [Allen](#)
Sent: Tuesday, June 26, 2007 12:37 PM
Subject: HOMS products 82669-1 and 86992-2

Raderrio:

Last Thursday I submitted two Notifications, one for each of the HOMS products (lotion and spray). They were received at the Agency at 11.25 am on Friday June 22, 2007 and signed for by D. Allen. These notifications were restricted to (a) notification of an additional brand name, and (b) the combining of two claims from the original March 15 stamped approved labels namely "Repels ticks that may transmit Lyme Disease for up to 2 hours" and "Repels ticks that may transmit Rocky Mountain Spotted Fever" into one

combined claim "Repels ticks that may transmit Lyme Disease and Rocky Mountain Spotted Fever for up to two hours."

I believe that these changes do qualify as a notification covered by PRN 98-10. We should like as soon as possible get these products legally into the channels of trade and so if you let me know that the notifications are acceptable to BPPD, then I will have copies of finished product labels (identical to the draft labels submitted) sent to you before the end of the week so that Mr. Jones can label and distribute his products.

Regards,
Iain

Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive,
Goodyear, AZ 85338
623-535-4060 T
623-535-4061 F
jazkatz@quest.net

Linda Hollis/DC/USEPA/US

Linda Hollis/DC/USEPA/US

07/12/2007 09:30 AM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc Andrew Bryceland/DC/USEPA/US@EPA,
cole.leonard@epa.gov

Subject Re: Fw: HOMS products 82669-1 and 86992-2

Raderrio: Yes Leonard informed me of that. I have yet to respond to Iain because I am still trying to wrap my arms around the main issue. I conferenced with Leonard yesterday for about one hour regarding this issue. We went thru the jacket piece by piece to first ensure that the efficacy claims were supported. Seems as though for mosquitoes they had supporting data for up to 8 hours but elected to put four hours of control on the label. As for ticks, it appears as though they had supporting data for 2 hours. I have the information twisted but at any rate on their stamped label, the hours for protection seemed okay. I understand that one of their requests was for to combine the claims for controlling mosquitoes and ticks for 2 hours. Given that their data support this and unless our guidance as indicated in 98-10 dictates that you can not combine claims for different pests, it appears that this would be okay. One of the things that Andy would look for in his triage of the submission would be that and determine if both requests are true notifications or fast tracks.

So we need to double check. As I understand it, another one of their claims was an alternate brand name. The alternate brand name was block bitter or something. My experience in BPB with at least two other cases is that the term "block" is not allowed. It represents some confusion as the product actually repels and block implies stronger control than what really is and thus we have not allowed it. I also understand that we did in fact allow that term on the Master label. If this is the case, we will need to correct this, and alert the registrant to remove the claim. I had asked Leonard to take the jackets home as well as the notifications so that we could have reviewed them last night as I needed to see them.

Once I sift thru my emails regarding this product, I can get a true understanding of what really is the issue and why the company is doing something illegal and then I will respond to Iain.

His emails to you indicated that this was his third inquiry to you about the status of the notifications. I know that we did not receive them until June 28th, but prior to that, did you respond to him via telephone call or email that you nor the Agency were in receipt of the submissions. I need to know that because I will need

Raderrio
Wilkins/DC/USEPA/US
07/11/2007 12:06 PM

To Linda Hollis/DC/USEPA/US@EPA
cc Janet Andersen/DC/USEPA/US@EPA, Michael
Mcdavit/DC/USEPA/US@EPA, Leonard
Cole/DC/USEPA/US@EPA, Andrew
bcc
Subject Re: Fw: HOMS products 82669-1 and 86992-2

Linda,

I am appalled over Iain's inaccurate interpretation of our telephone conversation (June 19, 2007). His perpetual attempts to circumvent the Agency's process is becoming unacceptable. Iain's false and misleading allegation stem from a deficiency letter issued on June 19, 2007, where he submitted a multi-component application as a notification when it was adjudged to contain revisions as an amendment. Furthermore, he became irate when I informed him that the Agency was aware that his client was selling the products referenced above, on the market without having an approved stamped label from the Agency, in addition to making other misleading product marketing claims, Iain openly admitted this infraction to me over the telephone in the presence of Leonard. I informed him that his client's registration will be subjected to cancellation in accordance with FIFRA sect. 6(e) if the company did not comply with the Agency's policy. On June 20, 2007, BPPD received a formal letter disclosing HOMS LLC involvement in shipping their products to two retail accounts (Kerr Drug (local NC Chain) and Magellans Travel Supply (California mail order catalog). To date, the notifications in question were received by BPPD on Friday, June 28, 2007 and have not been assigned in OPPIN by the appropriate Team Captain.

Sincerely,
Raderrio Wilkins

"jatzkatz" <jatzkatz@qwest.net>



"jatzkatz"
<jatzkatz@qwest.net>
07/11/2007 12:28 AM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc Linda Hollis/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA
Subject Fw: HOMS products 82669-1 and 86992-2

Raderrio:

This is the third reminder, requesting information regarding the Notification of the HOMS mosquito repellent products. I realize that you have told me that the financial state of any company is not your concern, however I would have thought the loss of two novel registrations would be of concern, if not to you, to the Agency.

I am out of the office tomorrow (Wednesday) and Thursday but if you leave a voicemail at 623-535-4060 I will be able to pick it up and let HOMS know to print labels.

Regards,
Iain

----- Original Message -----

From: jatzkatz
To: Wilkins.Raderrio@epamail.epa.gov
Cc: Allen ; Hollis.Linda@epamail.epa.gov
Sent: Thursday, June 28, 2007 9:26 AM
Subject: Fw: HOMS products 82669-1 and 86992-2

Raderrio:

I am following up on Tuesday e-mail (see below) since every day counts and if these products do not get into the channels of trade then their future is in jeopardy. I realize as you said when we spoke last that the EPA is not responsible for the financial solvency of companies however it will alleviate the HOMS situation if these products can get to the market place by next week.

We are fast approaching the point of no return to be able to market the products this year and I would rather not put the client in jeopardy by risking the printing, submission and use of the labels submitted on June 21, 2007.

Regards,
Iain

----- Original Message -----

From: jazkatz

To: Wilkins.Raderrio@epamail.epa.gov

Cc: [Allen](#)

Sent: Tuesday, June 26, 2007 12:37 PM

Subject: HOMS products 82669-1 and 86992-2

Raderrio:

Last Thursday I submitted two Notifications, one for each of the HOMS products (lotion and spray). they were received at the Agency at 11.25 am on Friday June 22, 2007 and signed for by D. Allen. These notifications were restricted to (a) notification of an additional brand name, and (b) the combining of two claims from the original March 15 stamped approved labels namely "Repels ticks that may transmit Lyme Disease for up to 2 hours" and "Repels ticks that may transmit Rocky Mountain Spotted Fever" into one combined claim "Repels ticks that may transmit Lyme Disease and Rocky Mountain Spotted Fever for up to two hours."

I believe that these changes do qualify as a notification covered by PRN 98-10. We should like as soon as possible get these products legally into the channels of trade and so if you let me know that the notifications are acceptable to BPPD, then I will have copies of finished product labels (identical to the draft labels submitted) sent to you before the end of the week so that Mr. Jones can label and distribute his products.

Regards,
Iain

Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive,
Goodyear, AZ 85338
623-535-4060 T
623-535-4061 F
jazkatz@quest.net



"jazkatz"
<jazkatz@qwest.net>
06/21/2007 12:37 PM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA
bcc
Subject BioUD Product Issues.

Dear Linda:

Over the last few days I have been trying correct the situation with these products which was caused by my filing of a multi-component application as a Notification when it was adjudged by the Agency to contain actions which they regarded as amendments. I have no fault with that, however subsequently in an e-mail after a conversation with Mr. Wilkins he put in an e-mail that I had "openly admitted that your client is selling the products referenced above.". This statement is untrue, I actually said that I had no direct knowledge of the products being sold but I suspected that they might, because of the haste to obtain the Notification and the filing of state registration."

Later in a conversation today I told Mr. Wilkins that I now had direct knowledge that no product had been sold (client misunderstood my question he thoughtn I had asked whether product had been sold over the internet) - however on asking further questions to my client I did find out that product had been sold. So having been caught up in a "I think they may have been offered for sale." then "I know they have not been offered for sale" to eventually finding out that they indeed were offered for sale I requested that the registrant wrie a letter detailing to you as to whether the products were offered for sale.

Therefore attached to this e-mail is a letter signed by the registrant reporting that some product was offered for sale, how much and to whom, and the remedies being taken to correct the matter.

Also, two notifications, one for each product will reach EPA tomorrow morning (Friday June 23, 2007) these notifications are based on the results of the todays conversation with Mr. Wilkins.

Regards,
Iain

Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338
623-535-4060 T
623-535-4061 F
jazkatz@qwest.net



AJONESLETTER.pdf

Bite **BLOCKER®** Tropical Insect Repellents

HOMS LLC
PO Box 724
120 North Tech Dr. Suite 103
Clayton, NC 27520
Tel: 888-270-5721
Direct: 919-550-0409
Fax: 919-553-6616

June 20, 2007

TO: Raderrio Wilkins and Linda Hollis,
Biochemical Pesticides Branch of United States Environmental Protection Agency

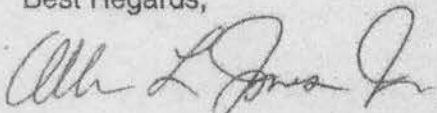
Reference: Letter by Linda Hollis dated Jun 19, 2007.

I have discussed the issues of our BioUD products with our EPA consultant, Dr. Iain Weatherston of Technology Sciences Group Inc. As a small company and this being our first BPPD registration, we are still learning the EPA process and viewed our marketing label as a notification based on the approved EPA label. HOMS has shipped product based on this understanding to two Retail Accounts: Kerr Drug (local NC chain) and Magellans Travel Supply (California mail order catalog). There were 480 bottles shipped to Magellans and 231 bottles shipped to Kerr Drug from May to June 2007.

Based on our updated knowledge regarding the difference between a notification and an amended label, HOMS will recall **all product** at these accounts and hold all manufactured product in our warehouse until we are able to re-label the product with an EPA approved label. We regret that our understanding of this process was not complete and respectfully wish to submit a label notification for your acceptance.

Our EPA representative, Dr. Iain Weatherston, will be following up with the label notification and any other requirements for us to be able to work through this issue.

Best Regards,



Allen L Jones, Jr., President
HOMS, LLC
120-103 North Tech Dr.
PO Box 724
Clayton, NC 27520
919-550-0409

HOMS LLC
Natural Solutions to Nature's Pests

Raderrio
Wilkins/DC/USEPA/US
06/20/2007 11:19 AM

To "jazkatz" <jazkatz@qwest.net>
cc "Allen" <allenj@homs.com>, Linda
Hollis/DC/USEPA/US@EPA, "Oleta Melnicoe"
<OMelnicoe@TSGUSA.COM>, rstewart@tsgusa.com, Clara
bcc
Subject Re: BioUD-8 Products [82669-1 and 82669-2]

Dear Dr. Weatherston:

Per our telephone conversation and faxed Notification rejection letter (dated June 19, 2007), you were informed of the following:

1) **Final Print Label (FPL):** Homs LLC failed to comply with the Agency's requirement by submitting three copies of their final printed labeling before releasing the product for shipment. On your client's Notice of Pesticide Registration Approval Letter (dated 3/15/07), the Agency informed you and/or Homs LLC that, "if this condition was not complied with, the registration will be subjected to cancellation in accordance with FIFRA sect. 6(e)". Furthermore, you openly admitted to me that your client is selling the products referenced above, on the market without submitting their FPL to the Agency.

2) **Repellency and Protection Claims:** The efficacy data submitted with your application for a Pesticide Registration and the Agency's Review (DER) determined a maximum repellency/protection for up to 4.5 hours for Mosquitos and 2 hours for Ticks, in contrast to an unlimited repellency. The stamped label (dated 3/15/07) has redundant labeling claims that must be deleted to prevent falsely, misleading the user (example: (1) Repels ticks for up to 2 hours - verses - Repels ticks that may transmit Lyme Disease and (2) Protection for 4.5 hours from Mosquitos that may transmit West Nile Virus - verses- Repels mosquitos that may transmit West Nile Virus).

3) **Graphic Symbol and Marketing Tag:** The addition of a graphic depicting a mosquito with a red band through the center and the marketing tag "Don't Get Bit" on the front panel of your label, is not an acceptable Notification under PR Notice 98-10. Symbols and graphics may be used in conjunction with and in close proximity to explanatory or instructional labeling text, provided they do not substitute or conflict with label text and are not false and misleading. The caption on the graphic shows a mosquito with a line through it's center which has nothing to do with showing the user how to apply the product.

Iain, please note that when you submit an application for a notification and/or label amendment, BPPD reserves the right to conduct a thorough review of your label to ensure labeling compliance and request revisions when needed. In closing, BPPD's screen of this request has been conducted for its applicability under PRN 98-10 and it has been determined that the action(s) requested does not clearly fall within the scope of PRN 98-10.

Sincerely,

Raderrio Wilkins

"jatzkatz" <jatzkatz@qwest.net>



"jatzkatz"
<jatzkatz@qwest.net>
06/19/2007 08:56 PM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc "Allen" <allenj@homs.com>, Linda
Hollis/DC/USEPA/US@EPA, "Oleta Melnicoe"
<OMelnicoe@TSGUSA.COM>, <rstewart@tsgusa.com>
Subject BioUD-8 Products [82669-1 and 82669-2]

Raderrio:

I have received and reviewed the "non-acceptable" letters for the notification for these two products. Before I discuss these with the registrant I need to clear up four items:

1] I am correct in saying that originally on the March 15, 2007 stamped approved labels the Agency **allowed** the following claims:

- Block the Bite
- Repels mosquitoes that may transmit West Nile Virus
- Repels ticks and other arthropods
- Repels ticks that may transmit Rocky Mountain Spotted Fever
- Repels ticks and mosquitoes that may transmit Lyme Disease
- (plus another 4 claims)

But now the Agency is **saying that all of the above claims must be removed** from the label because they do not state an approved duration.

If this is correct, then the offending label would be approvable if the second claim of the finished product label were to say "Repels ticks that may transmit Lyme Disease and Rocky Mountain Spotted Fever for up to 2 hours?"

2] The graphic symbol appearing on the spray product "Don't Get Bit" with the mosquito with a red bar through it, and underneath the phrase "Apply Directly to Skin and Clothing"

In our conversation today you said that symbols could only be added to the label by notification under PRN 98-10 Section II H when such symbols or graphics are used [text says **"may be used"** in conjunction with and in close proximity to explanatory label text, provided they do not substitute for, or conflict with label text, and are not false or misleading [as described in 40 CFR 156.10 (a)(5)]. The text also goes on to say "Examples include" - the following list is therefore exhaustive.

I need clarification of two points here (a) based on the above why then is "Don't get bit" and "Apply to skin or clothing" not acceptable - the tag is "Don't get bit" the explanatory text is "Apply to skin and clothing" is an approved use direction and the graphic indicates the pest is the mosquito. (b) this is an advertising tag and is not FIFRA related, under what regulation gives BBPD authority to ask for the removal

of this symbol. I would like to remind you that there are many products on the market which are for use against fleas and ticks on dogs which cannot be used on cats and the allowable symbol is a circle containing a depiction of a cat in a circle with a

red line through it. Also, if you look at the labels of several EPA approved labels for pet spot on products you will see that they contain multiple circles each with a pest inside and a red bar through it to indicate that the product is effective against all of these pests. There is one label with fleas, ticks, mosquitoes, lice and mites all depicted in this way. According to my research EPA exerts control over

"advertising" whether it be labeling or advertisements under FIFRA Section 12(a)(1)(B) and (E) neither of which are applicable here since "Don't Get Bit" is not a claim.

3] If the new submission is only denoting, the additional brand name, and correcting the claim by adding a duration (note this is at your instigation, the still current SAL approves the five claims shown above) can this be done by Notification?

4] If the new submission is only denoting, the additional brand name, correcting the claim by adding a duration (note this is at your instigation, the still current SAL approves the five claims shown above) and reinstitute the advertising tag and based on the explanations above can this be done by Notification?

Please respond in writing to the above questions and the registrant and I will decide on the next course of action and hopefully we will be able to get a new draft label to you by the beginning of next week.

Regards,

Iain



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Iain Weatherston, Ph.D.
Technology Science Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338

JUN 19 2007

Subject: Notification of Label Change

EPA Reg. No. 82669-2
Submitted: May 2, 2007

Dear Dr. Weatherston:

Your submission of May 2, 2007, concerning a labeling change to BioUD-8 Spray (EPA Reg. No. 82669-2), as modified, has been received and reviewed. The labeling is **not acceptable** as a notification per PR Notice 98-10 and must be resubmitted as a label amendment with the following corrections:

(a) Final Printed Label: Homs LLC failed to comply with the Agency's requirement by submitting three copies of the revised final printed labeling before releasing the product for shipment. On your Notice of Pesticide Registration letter (dated March 15, 2007), the Agency informed you that, "if this condition was not complied with, the registration will be subjected to cancellation in accordance with FIFRA sect. 6(e)".

(b) Alternant Brand Name: The request for an alternant brand name is permissible under 98-10, however, the label you submitted only showed the alternant brand name. When you resubmit your application as a label amendment, include a draft label, like the one stamped accepted with both the current product's name and the proposed alternant brand name.

(c) Remove Graphic Symbol: Symbols and graphics may be used in conjunction with and in close proximity to explanatory labeling text, provided they do not substitute or conflict with label text and are not false and misleading. The caption on the graphic instruct the user to apply the product directly to skin and clothing; which agrees with the direction for use, however, it shows a mosquito with a line through it which has nothing to do with showing the user how to apply this product.

(d) Revise Repellency Claims on front label: All efficacy and protection claims for this product must display a maximum repellency/protection interval of "**up to 4.5 for Mosquito and up to 2 hour protection for Ticks**".

It is not legal to sell or distribute this product as the proposed label is written. As required under 40 CFR section 152.44, an application to revise the labeling must be approved by the Agency before the above product may legally be distributed or sold. For any question you may have concerning this action, please contact Mr. Raderrio Wilkins at 703.308.1259 or email at Wilkins.Raderrio@epa.gov. We hope you find this information helpful.

Sincerely,

Linda Hollis

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division



Michael
McDavit/DC/USEPA/US
Sent by: Michael McDavit

05/15/2007 02:48 PM

To "Iain Weatherston" <IWeatherston@TSGUSA.COM>

cc Raderrio Wilkins/DC/USEPA/US@EPA, Linda
Hollis/DC/USEPA/US@EPA, Susan
Jennings/DC/USEPA/US@EPA

bcc

Subject Response to Your Email dated May 1, 2007, Re: BIOUD
PRODUCTS

Dear Mr. Weatherston,

Thanks for the phone call on 5/15/07, following up on your attached email. I'm sorry I have not gotten back to you sooner. I appreciate your efforts to address the statements of concern on the BioUD website

Your proposed corrections seem generally responsive to our concerns, although I ultimately defer to my EPA enforcement counterparts on the finer details of compliance. There are, however, still some obvious, offensive statements that need to be addressed. In particular, "Proven more effective than DEET" is still an unacceptable statement and is violative. In your proposed revision it would appear twice, I think. In any event, it is imperative that the website not make any comparative statements such as this. Under FIFRA, such statements are considered false and misleading.

Regarding the California review of the efficacy data, please feel free to provide a copy to the CDC. We maintain that the level of protection at which we registered the product is at most what the data support (ie., 4.5 hours for mosquito and 2.0 hours for tick). In our view, the CDPR review does not add or detract from our conclusions; it merely summarizes the findings and conclusions.

Please immediately address our concerns about the violative statements on the website and notify your client with appropriate revisions.

Best regards,

Mike McDavit

W. Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW (MC-7511P)
Washington, DC 20460
703-305-7761 (tel)
703-308-7026 (fax)

"Iain Weatherston" <IWeatherston@TSGUSA.COM>



"Iain Weatherston"
<IWeatherston@TSGUSA.COM>

05/01/2007 11:08 AM

To Michael McDavit/DC/USEPA/US@EPA

cc

Subject BIOUD PRODUCTS

Dear Mike

Following up on last Friday's conversation about the BioUD products recently registered to HOMS I promised you two items (a) information concerning the CDPR review of the efficacy data which was submitted to both agencies and which I had requested should be sent to CDC along with the submitted data and the EPA reviews, and (b) comments on how to bring the BioUD web-site into compliance with FIFRA 40 CFR 156 since there are both real and perceived issues.

(a) The complete CDPR reviews of data submitted in support of the registration of the two BioUD products in California was submitted to BPPD, to Raderrio Wilkins as an e-mail attachment on January 16, 2007 at 11.04 mountain time. If you so desire this e-mail plus attachment can be forwarded to you again. The CDPR reviews were again referenced in a deficiency letter rebuttal dated February 13, 2007 and I would ask you to note paragraphs 2, 3 and 4 on page 2 of the rebuttal. No response was ever received to my question (paragraph 3) as to whether the EPA reviewer had contacted her CDPR counterpart to discuss the studies and determine why their conclusions were so different. It would be a biased playing field if the EPA only gave CDC the HOMS data and the BPPD reviews without including the CDPR reviews.

(b) The HOMS BioUD website - I have been told that EPA believe it to be in violation of 40 CFR 156 and FIFRA Sects. 12(a)(1)(B) and 12(a)(1)(E). The only specific indication was that the Agency construed the link to EPA under the statement "What others are saying about BioUD" to be an endorsement of the product by the Agency. Also the relevance of the "green pharmaceuticals" paper authored by a senior EPA scientist was questioned - the paper mentions 2-undecanone, the active ingredient of the BioUD products.

Possibly the best idea is for me to go through the website, and if you pull the website up you can follow my comments, then if you give me a time and date I can call in to discuss the changes and hopefully this can be put to rest.

Home page:

BioUD The natural replacement to DEET

CHANGING the way you think about INSECT REPELLENT NATURALLY

Both of these statements are allowable, the first is a statement of fact 2-undecanone is a natural product found not only in tomatoes but in other plants and arthropods, and BioUD is a replacement to DEET. Now the customers have a choice of using DEET or a replacement product, BioUD. The second is clever marketing verbiage based on two of the several dictionary definitions of "naturally" - which can mean "arising from nature" which the product is based on the original work at NCSU in the isolation of 2-undecanone from wild tomatoes, another meaning of "naturally" is "as one might expect" or "of course" which relates back to the "BioUD The natural replacement to DEET"

The next statement about the formulation is again non-violative of the regulations and FIFRA citations given above when the word "safer" is removed. This will be changed to **BioUD: A formulation of a natural active ingredient isolated from a wild tomato plant and proven more effective than DEET as an insect repellent.**

The next paragraph will be changed to read "This patented compound is classified by the EPA as a Biopesticide product, products which are usually inherently less toxic than conventional pesticides. The active ingredient is also classified by the FDA as flavoring agent that may be safely used in food. The BioUD formulation contains emollients, is non flammable and is not a plasticizer. Data from tests conducted in the United States and Canada have shown that BioUD is more effective than DEET as a mosquito and tick repellent. HOMS received EPA approval of the BioUD registration on March 15, 2007 and will begin selling both a lotion and spray product through retailers world wide.

"What others are saying about BioUD" will be retained, however below will be written "The information given through these links is intended for educational purposes only and is not to be construed as an endorsement of BioUD products by the U.S. Environmental Protection Agency or any other Federal Agency. The links: USDA goes to a paper which was the lead article in the may 2005 USDA-CREES Plant Science Updates, the EPA link goes to a paper on green pharmaceuticals by an EPA scientist in which on page 7 in a paragraph on Naturally Occurring Personal care products, 2-undecanone and its properties are mentioned. When BPPD put a BioUD Fact Sheet (or 2-Undecanone Fact Sheet) on their website, the BioUD -EPA link will go to the fact sheet. The NCSU link is to an old (2005) press release about the work of Dr. Michael Roe at NCSU that led to these products. The HOMS link is to a paper entitled "The Best Bug Repellent is All Natural" and this refers to 40 CFR 152.25(f) materials and is exempt from FIFRA. None of these links or their contents are in violation of FIFRA.

Science Page: This is a link to the patent application of Dr. Roe and as such is exempt from FIFRA.

Endorsements: This is a film clip from a TV station in North Carolina talking generally about mosquitoes, the diseases they carry and their control, then footage in the laboratory of Dr Roe - there are no FIFRA violations.

BioUD Advantages: This is a copy of a poster presentation made by Dr. Roe at the Annual Meeting of the Entomological Society of America in Indianapolis in December 2006 and as such is outside of the scope of FIFRA.

Products: This is a link to HOMS other product lines which are exempt from FIFRA at 40 CFR 152.25(f)

Contact: This is a link to a preaddressed e-mail

Mike, I have attached another press release which just became available to me this morning, note that the reporter quotes an EPA headquarters staffer in the article. At this time I am worried that the CDC is not going to get the full picture if they only review the data submitted to EPA and the BPPD reviewers. I would like to make sure that they receive the CDPR data and I also believe that they should speak with the scientists who carried out the studies.

Turning now to the website - with the explanations given above together with the changes suggested I believe that the website is now not in violation of FIFRA. I will be here in the Arizona office for the remainder of the week and would like to discuss this situation with you. I can be reached at 623-535-4060 (just remember that we are now on Pacific Time and there is a 3 hour time difference).

Best regards,



Iain Weatherston EPA approved natural insect repellent post and courier[1].pdf

Receipt for Section 3

S: 810229 Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3 Fee For Service: ☒ Yes ☐ No

Application Type: Notification

Company: 82669 HOMES, LLC V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82669-2 Product Name: BIO-UD-B SPRAY

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 02-May-2007 OPP Rec'd Date: 04-May-2007

Front End Date: 04-May-2007 Risk Manager Send Date: 14-May-2007

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description: notification.

New Ingredient Request Date:

New Ingredient Received Date:

Receipt Content

art Welcome - Lotus Notes EPA-PRISM Main - Co... 10:37 AM

Notification Team = Andy

↓
5/23/07
4th

AIO-Andy
MAY 24 2007
sdh



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82669-2	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) BioUD-8 Spray	PM# 99	
5. Name and Address of Applicant (Include ZIP Code) HOMS LLC P.O. Box 724, Clayton Center, Clayton, NC 27520 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 3/15/2007
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

See separate page.

This notification is consistent with the provisions of PRN 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec.1001 to wilfully make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PRN 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	Other (Specify) _____	
		If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4.0 oz, 6.7 oz & 16.9 oz		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Iain Weatherston	Title Senior Regulatory Consultant	Telephone No. (Include Area Code) 623-535-4060	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Senior Regulatory Consultant		
4. Typed Name Iain Weatherston	5. Date May 2, 2007		

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 82669-2

Send to SIG: check box ☒

This material is:

- ☐ New stamped-accepted label
- ☐ New CSF
- ☒ Notification
- ☐ Final Printed Label
- ☐ Other: Please file in folder

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: L. Wilkins

Phone: _____ Division: BPPD

Date: _____

Label changes made by notification as per PRM 98-10

1. HOMS LLC is submitting an alternate brand name for this product. The product will be market as:

HOMS Bite Blocker BioUD Insect Repellent & Clothing Treatment

This name is already used on the finished product labeling submitted in this package.
Notification as per PRN 98-10 IIA

2. HOMS is adding to the label by notification an optional claim:

"Repels ticks that may transmit LYME DISEASE and ROCKY MOUNTAIN SPOTTED FEVER"

To make the best use of space available three approved claims have been condensed.
Approved claims include:

"Repels ticks that may transmit Rocky Mountain Spotted Fever," "Repels ticks that may transmit LYME DISEASE for up to two hours" and "Repels ticks and mosquitoes that may carry LYME Disease."

Notification as per PRN 98-10 IIE - the small package does not allow for the printing of the three separate claims. The notification is consistent with all of the criteria at IIE.

3. HOMS is adding to the label by notification the graphic depicting a mosquito with a red stripe through it. Above the icon is a marketing tag "Don't Get Bit," and below the icon is the optional text, "Apply directly to skin and clothing."

Notification as per PRN 98-10 IIH and IIN 3 and Non-Notification (Don't get bit) IVF1.

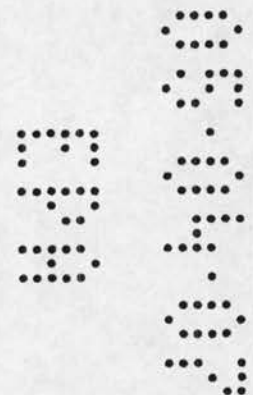
4. HOMS is adding by non notification (included here for completeness) the addition of metric units to the Net Contents statement.

Non-Notification as per PRN 98-10 IVC

5. HOMS is changing by non-notification the verbiage

"EPA Establishment Number" to "EPA Est. No."

Non-notification as per PRN 98-10 IVA



Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net

Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division



May 2, 2007

Notification Coordinator (BPPD)
Document Processing Desk (NOTIF)
U.S. EPA - Office of Pesticide Programs
One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

Dear Sir/Madam:

SUBJECT: Notifications of label verbiage changes and submission of final printed labeling.

COMPANY: HOMS LLC
P.O. Box 724
Clayton Center
Clayton, NC 27520

CONTACT: Iain Weatherston, Ph.D.
(Contact information as per letterhead)

PRODUCTS: BioUD-8 Lotion [82669-1] and BioUD-8 Spray [82669-2]

*2-SUBMISSIONS
Included
Here*

As agent for, and on behalf of HOMS LLC I submit to you three copies of each of the newly registered designated products.

In addition to, and incorporated into this labeling are the following changes:

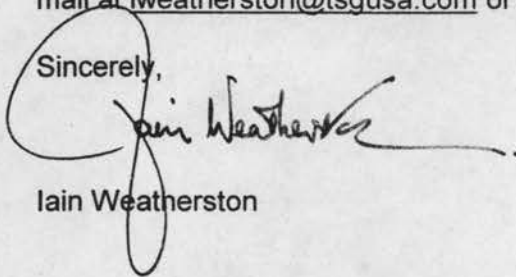
- 1] An additional brand name of HOMS Bite Blocker BioUD Insect Repellent 1 for the lotion product with EPARN 82669-1] and HOMS Bite Blocker BioUD Insect Repellent and Clothing Treatment.
- 2] Optional claim "Repels ticks that may transmit LYME DISEASE and ROCKY MOUNTAIN SPOTTED FEVER.
- 3a] The addition of a graphic depicting a mosquito and a tick containing also claim verbiage already approved by EPA. [lotion product only].
- 3b] The addition of a graphic depicting a mosquito with a red band through it, above the graphic is the marketing tag "Don't Get Bit" and below it the optional text "Apply directly to skin and clothing."
- 4] Three non-notification items (a) addition of metric units, (b) truncation of the phrase EPA Establishment Number to EPA Est. No. and (c) the addition of a marketing tag "Don't Get Bit," - this is on the spray label and may appear on a later label iteration of the lotion product.

In addition to this letter, the package contains for each product::

- Three finished product labels (black and white artwork).
- Completed application for pesticide [8570-1] with required certification.
- One page explanation of the changes to the label being notified.
- One copy of each of the SAL for the products
- One marked up label showing the changes made in the finished product labeling.

If you have any questions or require further information of explanation please contact me by e-mail at iweatherston@tsgusa.com or by phone at 623-535-4060.

Sincerely,

A handwritten signature in black ink, appearing to read "Iain Weatherston", with a large, stylized loop at the end of the signature.

Iain Weatherston

REFER TO ONE PAGE EXPLANATION SHEET.

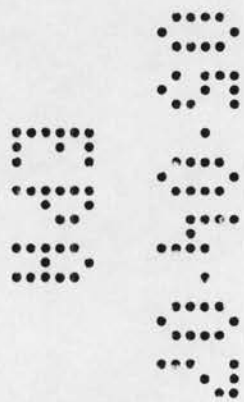


PRECAUTIONARY STATEMENTS:

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. **FIRST AID: IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person. **IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. **HOT LINE NUMBER:** Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9:30 am and 7:30 pm) for emergency treatment advice. **DIRECTIONS FOR USE:** It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Read all directions before using this product. An adult should apply this product to children under 10 years of age. Do not allow children to apply this product. **GENERAL INSTRUCTIONS:** Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 hours. For added protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 4.5 hours or after swimming, toweling or vigorous activity. (Wash treated areas of skin with soap and water after returning indoors).

STORAGE AND DISPOSAL **STORAGE:** Store in original container in a cool, dry area inaccessible to children. **DISPOSAL:** Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container. **IF PARTIALLY FILLED:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain. Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com.

HOMS, LLC P.O. BOX 724,
CLAYTON, NC 27520





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 17 2007

Emily Zielinski-Gutierrez, Ph.D.
Division of Vector-Borne Infectious Diseases
National Center for Zoonotic, Vector-Borne and Enteric Diseases
Centers for Disease Control and Prevention
P.O. 2087
Fort Collins, CO 80522

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Dear Dr. Gutierrez,

This letter is in response to your request of April 9, 2007 for efficacy information that has been submitted to the Agency to support registration of BioUD, a biochemical pest control agent that repels mosquitoes and ticks.

We have enclosed the following in this package which has been cleared for confidential business information content:

- Product performance reports for Bio-UD-8 spray by Weatherston, et. al. Technology Sciences Group Inc. March 1, 2006.
- Memo on Response to Study Design Concerns. InTox Biotech. February 8, 2007.
- Rebuttal of the Deficiency Letter Regarding the Performance of the data submitted to support Bio-US-8 spray. February 10, 2007
- Science Review of Efficacy Data Supporting Registration of Bio-US-8 Spray by Dr. Clara Fuentes, USEPA. February 21, 2007.

You are reminded that the responsive records that are otherwise exempt from public disclosure shall not be further disclosed to anyone without the written permission of the U.S. Environmental Protection Agency.

If there is any further information you need, please do not hesitate to contact Candy Brassard at 703-305-6598.

Sincerely,

A handwritten signature in cursive script that reads "Michael McDavit".

Michael McDavit, Associate Director
Biopesticides and Pollution Prevention Division



<http://www.epa.gov/pesticides/foia/aform.htm>
Last updated on Wednesday, January 17th, 2006
**Pesticides: Freedom of Information Act
(FOIA)**

You are here: EPA Home [Pesticides](#) [About Pesticides](#) [Information Sources](#) [FOIA Home](#)
Page [Affirmation of Non-Multinational Status Form](#)

Affirmation of Non-Multinational Status Form

This affirmation is required by the EPA interim procedures to implement Section 10 (g) of the Federal Insecticide, Fungicide, and Rodenticide Act.

I have requested access to information submitted by an applicant or registrant under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) to the Environmental Protection Agency. I hereby affirm that:

This affirmation is required by the EPA interim procedures to implement Section 10 (g) of the Federal Insecticide, Fungicide, and Rodenticide Act.

I have requested access to information submitted by an applicant or registrant under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) to the Environmental Protection Agency. I hereby affirm that:

1. I am not a business, or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States; and I am not an employee or agent of any such business or entity
2. I do not seek access to the information for purposes of delivering it or offering it for sale to any such business or entity or its employees or agents
3. I will not purposefully deliver the information (or negligently cause it to be delivered) to any such entity or to any of its employees or agents.

I am aware that I may be subject to criminal penalties under 18 U.S.C. 1001 if I have made any statement of material facts knowing that such statement is false or if I willfully conceal any material fact.

Date Apr 12, 2007 Signature Emily C. Zielinski
Name Emily C. Zielinski-Gutierrez
Address 3150 Rampart Road, Foothills Campus, Fort Collins CO 80521
Organization CDC/NCID/DVBID

Check one:

☒ I am not requesting access on behalf of someone else.

☐ I am requesting access on behalf of someone else. My client is:

Client _____ Organization _____

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

82669-2

Date of Issuance:

3/15/07

NOTICE OF PESTICIDE:

☒ Registration ☐ Re-registration
(under FIFRA, as amended)

Term of
Issuance:

Unconditional

Name of Pesticide Product:

BIO-UD-8 SPRAY

Name and Address of Registrant (include ZIP Code):

HOMS L.L.C
PO BOX 724
Clayton Center
Clayton, NC 27520

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA Sec. 3(c) (5) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 82669-2"
3. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Janet L. Andersen
Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division

Date:

3/15/07

CONCURRENCES

SYMBOL	7511P	7511P	7511P				
SURNAME	R. W. King	COLE	HOLLIS				
DATE	3/12/07	3/15/07	3/15/07				

Front panel

BIO-UD-8 Spray

Repels mosquitoes for 4.5 hours

Protects against mosquito borne diseases
for 4.5 hours

Block the Bite

Repels mosquitoes that may transmit
West Nile Virus

Repels ticks that may transmit
Lyme Disease for up to 2 hours

Repels mosquitoes that may carry West Nile Virus for
4.5 hours.

Protection for 4.5 hours from
mosquitoes that may transmit West Nile Virus

Repels ticks and other arthropods

Repels ticks that may transmit Rocky
Mountain Spotted Fever *up*

Repels ticks and mosquitoes that
may transmit Lyme Disease

ACTIVE INGREDIENT

2-Undecanone [CAS# 112-12-9]

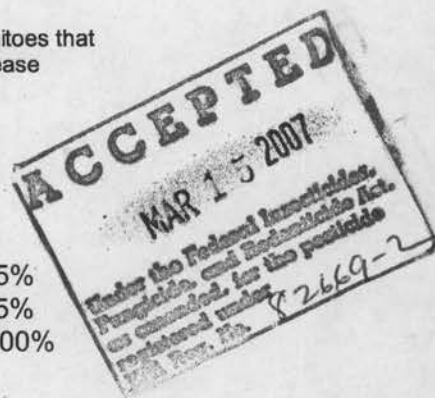
7.75%

OTHER INGREDIENTS

92.25%

TOTAL

100.00%



KEEP OUT OF REACH OF CHILDREN

CAUTION

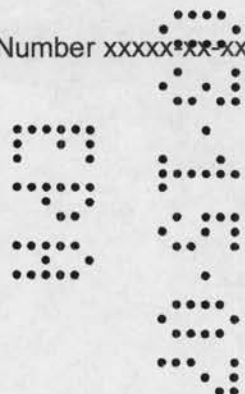
[See back panel for additional precautionary statements and the directions for use]

EPA Registration Number 82669-E

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

Iteration 4 [031507]



PRECAUTIONARY STATEMENTS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9.30 am and 7.30 pm) for emergency treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product.

An adult should apply this product to children under 10 years of age.

Do not allow children to apply this product

General Instructions:

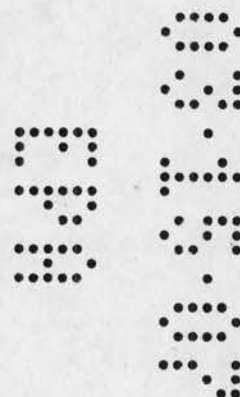
Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 hours. For added protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 4.5 hours or after swimming, toweling or vigorous activity. Wash treated areas of skin with soap and water after returning indoors].

STORAGE AND DISPOSAL

Storage:	Store in original container in a cool, dry area inaccessible to children
Disposal:	Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.
If partially filled:	Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520





Heather Bjornson
<HBjornson@TSGUSA.COM
>

03/15/2007 11:40 AM

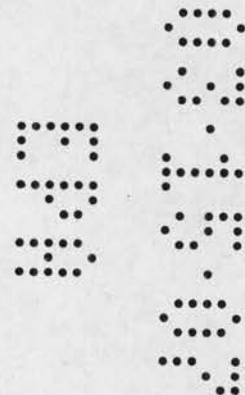
To Raderrio Wilkins/DC/USEPA/US@EPA
cc Iain Weatherston <jazkatz@qwest.net>
bcc
Subject Labels for HOMS

Raderrio-
As Iain Weatherston has requested, I am attaching the revised labels for HOMS L.L.C.

Regards,
Heather R. Bjornson
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 1000
Washington DC 20036
Tel.: (202) 828-8945
Fax: (202) 872-0745



LOTIONLABELITERATION4.pdf SPRAYLABELITERATIION4.pdf



Front panel

BIO-UD-8 Spray

Repels mosquitoes for 4.5 hours

Protects against mosquito borne diseases
for 4.5 hours

Block the Bite

Repels mosquitoes that may transmit
West Nile Virus

Repels ticks that may transmit
Lyme Disease for up to 2 hours

Repels mosquitoes that may carry West Nile Virus for
4.5 hours.

Protection for 4.5 hours from
mosquitoes that may transmit West Nile Virus

Repels ticks and other arthropods

Repels ticks that may transmit Rocky
Mountain Spotted Fever *up*

Repels ticks and mosquitoes that
may transmit Lyme Disease

ACTIVE INGREDIENT

2-Undecanone [CAS# 112-12-9] 7.75%

OTHER INGREDIENTS 92.25%

TOTAL 100.00%

Added Signal Word?
KEEP OUT OF REACH OF CHILDREN

CAUTION
DO NOT LET CHILDREN APPLY PRODUCT

[See back panel for additional precautionary statements and the directions for use]

EPA Registration Number 82669-E

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

Iteration 3 [030707]

*Please make
the following
corrections*
1. Add Signal Word
2. Relocate the
instruction to
Dir. for use.
3. Revise
Dir for use
4. Revise
Storage
Signal

*move to be placed
under direction
for use*

PRECAUTIONARY STATEMENTS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

HOT LINE NUMBER

Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9.30 am and 7.30 pm) for emergency treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product.

An adult should apply this product to children under 10 years of age.

(Do not allow children to apply the product)

General Instructions:

Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 hours. For added protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 4.5 hours or after swimming, toweling or vigorous activity. [Wash treated areas of skin with soap and water after returning indoors].

STORAGE AND DISPOSAL

Storage:

Disposal:

If partially filled:

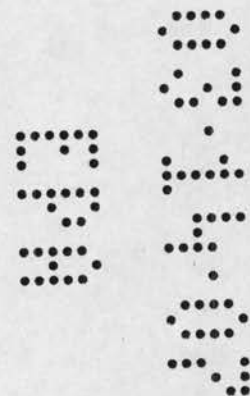
~~Do not contaminate~~
Store in original container in a cool, dry area inaccessible to children

Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.

Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520



4273

1984-585-829



Iain Weatherston
<jazkatz@qwest.net>
03/08/2007 10:04 AM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc
bcc
Subject BIO-UD-8 LABELS

Raderrio:

I reviewed the DER from Clara dated February 21, 2007 which you kindly sent a couple of days ago, and am in agreement with the contents.

Attached as you requested is what I hope will be the final iteration of these initial product labels. I have changed them to exactly reflect the "marked up" labels. Since this is the final step in the review process I look forward to receiving the approvals soon.

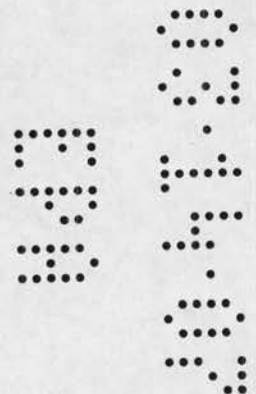
Should there be any questions just contact me and I will respond immediately.

Regards,
Iain

Iain Weatherston
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338
623-535-4060 [T]



jazkatz@qwest.net LOTIONLABELITERATION3-hrb.pdf SPRAYLABELITERATION3-hrb.pdf



Front panel

note:
this label
was for the
Regulation on
3/7/07 for
Coville
D. Williams

Please
Make
Corrections

Please remove
6 hours from
protection
statement

BIO-UD-8 Spray

Repels mosquitoes for 4.5 to ~~6~~ hours

Protects against mosquito borne diseases
for 4.5 to ~~6~~ hours

Block the Bite

Repels mosquitoes that may transmit
West Nile Virus

Repels ticks that may transmit
Lyme Disease

Repels mosquitoes that may carry West Nile Virus for
4.5 to ~~6~~ hours.

Protection for 4.5 to ~~6~~ hours from
mosquitoes that may transmit West Nile Virus

Repels ticks and other arthropods

Repels ticks that may transmit Rocky
Mountain Spotted Fever

Repels ticks and mosquitoes that
may transmit Lyme Disease

ACTIVE INGREDIENT

2-Undecanone [CAS# 112-12-9] 7.75%

OTHER INGREDIENTS 92.25%

TOTAL 100.00%

Keep out of Reach of Children

[See back panel for additional precautionary statements and the directions for use]

EPA Registration Number 82669-E

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

Iteration 2 [011107]

PRECAUTIONARY STATEMENTS

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes and skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

FIRST AID

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

IF IN EYES

- Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Add →
Hot line number
Have product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact the National Pesticide Information Center at 1-800-858-7378 (between 9.30 am and 7.30 pm) for emergency treatment advice.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product.

An adult should apply this product to children under 10 years of age.

General Instructions:

Shake well before using. This bottle is designed to spray upside down. For best results spray skin every 4.5 ~~6~~ hours. For added protection apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 4.5 ~~6~~ hours or after swimming, toweling or vigorous activity.

1.

*Delete
"6"*

Delete "6"

STORAGE AND DISPOSAL

Storage:	Store in original container in a cool, dry area inaccessible to children
Disposal:	Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.
If partially filled:	Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-888-270-5721 (between 9 am and 5 pm eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520



Iain Weatherston
<jazkatz@qwest.net>
03/07/2007 09:56 AM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc
bcc
Subject BIO-UD-8 SPRAY & BIO-UD-8 LOTION

Raderrio:

Following on from our conversation a few minutes ago you have permission to e-mail to me the product performance DER for the two products.

I also understand that you will e-mail as attachments copies of the two draft labels marked up with necessary corrections. I will discuss these with Allen Jones of HOMS, make the corrections and get electronic copies of the labels back to you as soon as possible, hopefully by noon Arizona time today.

Regards,
Iain

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 27 2007

Technology Sciences Group Inc.
c/o Iain Weatherston, Ph.D.
4061 North 156th Drive
Goodyear, AZ 85338

Re: Application for a Biopesticide Registration
BIO-UD-8 Spray
EPA Reg. No. 82669-E
Your submission of October 18, 2006

Dear Dr. Iain Weatherston

The product performance data for a Biopesticide registration referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been reviewed by BPPD and is unacceptable for the following reasons:

1. Verify that the test material cited in the study is the actual formulation submitted to support this registration, containing 7.75 % w/w methyl nonyl ketone (or 2-undecanoone) as its active ingredient.
2. The product performance data does not support the proposed labeling claim, "that the product protects against mosquitoes and ticks for 4.5 to 6 hours". The products tested contained dermatone and 8% undecanone as the active component and therefore, it is uncertain whether the test material used in the study was the actual product submitted for registration.
3. The labeling claim for repellency against ticks and other arthropods is unacceptable: the experimental design lacked replications. The same ticks were tested for consecutive periods and data was not statistically analyzed. It is uncertain whether the formulations tested were indeed the actual product proposed for registration.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B65) of six months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the

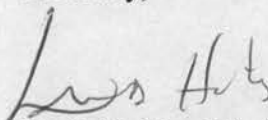
PRIA decision date of March 26, 2007 for you to submit the information requested above and for

SYMBOL	BPPD to complete the review and make a regulatory decision.					
SURNAME	[Signature]					
DATE	2/27/07					

If you can submit the required data to BPPD on or before February 13, 2007, you may renegotiate the due date or withdraw the application and resubmit when you can address the deficiencies or the Agency will issue a can not grant letter under PRIA on or about March 26, 2007. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately or within five (5) days from the date of this letter at (703) 308-1259 with your response.

Sincerely,

A handwritten signature in dark ink, appearing to read "Linda Hollis", is written over the typed name.

Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511C)

InTox Biotech

February 8, 2007

TO: HOMS, LLC

FROM: Dr. R. Michael Roe, Ph.D.
President of InTox Biotech

On Feb. 8, 2007, HOMS provided in an email an EPA Excerpt which stated the following: "The labeling claim for repellency against ticks and other arthropods is unacceptable: the experimental design lacked replications. The same ticks were tested for consecutive periods and data was not statistically analyzed. It is uncertain whether the formulations tested were indeed the actual product proposed for registration."

The following is my response to this review of my data and report:

1. EPA excerpt, "the experimental design lacked replications."

Roe response: **Report on American dog tick;** page 2, lines 15-16, "No ticks used were ever re-used except when a control and treatment test was conducted on the same day." Pages 11-12 (Table 5) is the results for replicate 1 for Bio-UD-8-lotion conducted on May 12, 2005; pages 13-14 (Table 6) is the results for replicate 2 for Bio-UD-8-lotion conducted on September 27, 2005; Pages 15-16 (Table 7) is the results for replicate 3 for Bio-UD-8-lotion conducted on September 28, 2005. **Report on deer tick;** Page 1, lines 3-4, "BioUD-8 on human skin was shown in replicated experiments to be repellent to the deer tick...." Page 2, lines 8-9, "No ticks used were ever re-used except when a control and treatment test was conducted on the same day." Pages 4-6 (Table 1) is the results for replicate 1 for Bio-UD-8-spray conducted on October 12, 2005; Pages 7-9 (Table 2) is the results for replicate 2 for Bio-UD-8 spray conducted on October 13, 2005; Pages 10-12 (Table 3) is the results for replicate 3 for Bio-UD-8-spray conducted on October 13, 2005.

In summary, in both tick reports each replicate of the original data collected is presented in separate tables; this must be considered as true replicated data because in the description of the methods for each report, it is stated that ticks were not reused for these experiments.

2. EPA excerpt, "The same ticks were tested for consecutive periods"

Roe response: As explain in item 1, the same ticks were not used between replicates. It is correct that the same ticks were used within each replicate to obtain a time course of the tick response after its first exposure to the repellent after 2 h on the skin of the human subject. A time course is required in a behavioral test because an animal's response to a repellent is not immediate; time is needed for the tick to respond to the repellent and make its choice. A single time point measurement is not appropriate because the ticks could be moving randomly and only a snapshot in time could provide incorrect information. Note that all of the responses in the time courses obtained except for the moment the ticks were exposed to the skin show repellency (a discussion of statistics to validate this conclusion will follow under item 3).

3. EPA excerpt, "data was not statistically analyzed"

Roe response: The results for both the American dog tick and deer tick were clearly repellent for the entire time course for all replicates. For example, in the case of the deer tick, the repellency for the three treatment replicates 15 min after being exposed to the treated skin was 100% with no variation between replicates; in case of the American dog tick for the three treatment replicates, the repellency after 15 min was 89% with almost no variability between replicates. Using the Proc Freq statement and an exact binomial test procedure in SAS/STAT (SAS. 2001. SAS/STAT Software Version 802. SAS Institute Inc., Cary, NC, USA), repellency for the deer tick for the three treatment replicates is significant with a P value of 0.0000038; for the American dog tick for the three treatment replicates, the P value is 0.00066.

4. EPA excerpt, "It is uncertain whether the formulations tested were indeed the actual product proposed for registration."

Roe response: In item 1 above, the location of each replicate of data for the American dog tick and deer tick in my reports are given. Each replicate is given in a separate table as also identified in item 1. In the title of each of these tables, the repellent is identified as Bio-UD-8 lotion for the American dog tick or Bio-UD-8-spray for the deer tick.

I hope this information answers your questions. Please feel free to contact me (919-280-2319; michael_roe@ncsu.edu) if you need any further information.

Raderrio:

Following up on your comment today that you were of the opinion that Clara indicated the products used by HOMS in the product performance studies were not the same as the products for which we are seeking approval. If your understanding of her comments is correct the she (Clara) is wrong. Her confusion may have been caused because as was pointed in the deficiency letter dated September 13 page 2 point 4 we had in the various tests and hence the reports used several different names for the products eg Code UD-8, Bio-UD-8 Tropical, HOMS Bio-UD-8 and BioBlock. In our response (Volume 82669-RESPONSE-1) submitted October 16, 2006 we admitted (Page 6 of 24) to using several names and agreed to from then on only use Bio-UD-8 Lotion and Bio-UD-8 Spray.

On behalf of HOMS I contend that in all of tests against mosquitoes and ticks used the two products for which we seek approval. If you review the efficacy volume [MRID 46783509] you will see that there are essentially six tests.

#1 pages 6-9 Bio-UD-8 lotion mosquitoes

#2 pages 11-14 Bio-UD-8 lotion mosquitoes

#3 pages 15-27 BioBlock with 2-undecanone (the spray) mosquitoes

#4 pages 28-39 Bio-UD-8 spray ticks

#5 pages 40-64 Bio-UD-8 spray and lotion ticks

#6 page 65 Bio-Ud-8 lotion mosquitoes

I believe that at this stage we have properly addressed all of the deficiencies and look forward to an expedited approval in the very near future.

Best regards,

Iain

Iain Weatherston, Ph.D.

Technology Sciences Group Inc.

4061 North 156th Drive,

Goodyear, AZ 85338

623-535-4060 [T]

jazkatz@qwest.net

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Raderrio Wilkins
Biochemical Pesticide Branch
U.S. EPA - OPP - BPPD
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

February 10, 2007

Dear Raderrio:

SUBJECT: Rebuttal of the latest "deficiency letter" regarding the product performance data submitted in support of Bio-UD-8 registrations. This draft was received as an e-mail attachment on February 8, 2007

COMPANY: HOMS L.L.C.
P.O. Box 724
Clayton Center
Clayton, N.C. 27520

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
[contact information as per letterhead]

PRODUCTS: Bio-UD-Lotion [82669-R] and Bio-UD-8 Spray [82669-E]

Deficiencies:

- 1] *"Please verify that the test material cited in **the study** is the actual formulation submitted to support the registration containing 7.75 % w/w methyl nonyl ketone (or 2-undecanone) as active ingredient."*

Response:

There is no way of knowing to which efficacy study your referring, however it is immaterial since in all studies, product chemistry, toxicology and efficacy were carried out with formulations containing 7.75% 2-undecanone, and furthermore these are the formulations for which registration is being sought. So by this statement I am verifying that Bio-UD-8 Lotion [82669-R] and Bio-UD-8 Spray [82669-E]:

- a) are the products for which registration is sought
- b) contain 7.75% w/w 2-undecanone as the nominal concentration of active ingredient
- c) are formulations which have been tested in the studies detailed in the volume identified as MRID 46783509.

This information was previous given to you, in an e-mail dated January 24, 2007 and titled HOMS Bio-UD-Efficacy Studies, a copy of this e-mail is attached to this letter.

- 2] *"The product performance data does not support the proposed labeling claim 'that the product protects against mosquitoes for 4.5 to 6 hours' The products tested contain dermatone and 8% undecanone. It is uncertain whether the test material was the actual product submitted for registration."*

Response

Taking the second part of the statement first, this has been previously addressed, firstly on page 6 of 24 in Volume 82669-RESPONSE-1 submitted to BPPD on October 16 2006, and again in an e-mail dated January 24, 2007. In these latter documents it is explained that previously in various documents the products for which registration is being sought were referred to as Bio-UD-8, Code UD-8, Tropical HOMS Bio-UD-8 and BioBlock and BioBlock with 2-undecanone. HOMS agreed that this was confusing and agreed to refer in all future correspondence etc., only to Bio-UD-8 Lotion and Bio-UD-8 Spray as the products for which registration is being sought. It should be noted here registration is not being sought for any product containing Dermatone. In one of the tests one of the test articles was named BioBlock with Dermatone; in another test a Bio-UD-30 Spray was tested, these were merely test articles for which data are given however these particular data are not being relied upon to substantiate the claims of repellency nor the duration of the repellency.

That the claims duration has not been demonstrated is patently not true. Regarding the mosquitoes for example I refer you to Tables 1, 2 and 3 (pages 23-26 in MRID 46783509). In particular this is clearly expressed in the summary table on page 26. Regarding the ticks, in two studies repellency was shown for 2 to 2.5 hours. In a third test (against American Dog Ticks) filter paper to which Bio-UD-8 had been applied was repellent to the ticks more than 9 hours after the application. However, in the labels being sought the tick claims is one of repellency with no duration stated, and the data unequivocally demonstrates repellency, and even greater repellency than an EPA registered product containing 7% DEET

Previously submitted to BPPD was the data evaluation report of CDPR who have approved these products for registration. In the report submitted to you was the efficacy reviews by Dr. Ghazanfari. Considering the public pronouncements from the EPA regarding sharing and acceptance of data reviews, etc. with both CDPR and PMRA we are interesting in knowing whether the EPA efficacy reviewer was ever shown the submitted evaluation report, and if so was there any communication with Dr. Ghazanfari? If the BPPD reviewer still believes that both the mosquito and tick claims have not been substantiated (not withstanding our rebuttals and the CDPR evaluation report) then the scientists involved are willing to meet with the reviewer and other BPPD staff to explain their results and discuss why they believe the studies support the claims. This however would have to be done on a time frame that does not result in BPPD wanting to yet again "renegotiate the PRIA date."

I have today reviewed again the draft label claims and I believe that we have substantiated each and every one of them. However, the claim "Repels ticks and other arthropods" we would be willing to remove from the label at this time as being too general although mosquitoes are arthropods, and come back in later as part of a label amendment.

- 3] *"The labeling claim for repellency against ticks and other arthropods is unacceptable; the experimental design lacked replications. The same ticks were tested for consecutive periods and data was not statistically analyzed. It is uncertain whether the formulations tested were indeed the actual product proposed for registration."*

Response

In response to this point please review the attached response prepared for HOMS by the UNC scientists that conducted the studies.

Raderrio, these responses fully address the points in your February 8, 2007 e-mail, the responses have been delivered in the time-frame I indicated and hence we look forward to an approval by March 26, 2007.

Sincerely,

Iain Weatherston

attachment:\ January 24, 2007 E-mail I. Weatherston to Raderrio Wilkins "HOMS Bio-UD-8 Efficacy Studies."
Response of Dr. R. Michael Roe

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

FACSIMILE COVER SHEET

[703-305-0118]

TO: RADERRIO WILKINS, BIOCHEMICAL PEST CONTROL AGENT BRANCH

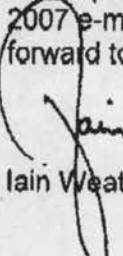
FROM: IAIN WEATHERSTON

DATE: FEBRUARY 10, 2007

SUBJECT: REBUTTAL OF EFFICACY DEFICIENCIES CONTAINED IN YOUR E-MAIL OF FEBRUARY8, 2007

Raderrio:

This 7 page fax (including cover) is the response which address all points in your February 8, 2007 e-mail. This has been delivered to you within the time-frame I indicated so we look forward to receiving both product approvals soon.


Iain Weatherston

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4080
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Raderrio Wilkins
Biochemical Pesticide Branch
U.S. EPA - OPP - BPPD
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

February 10, 2007

Dear Raderrio:

SUBJECT: Rebuttal of the latest "deficiency letter" regarding the product performance data submitted in support of Bio-UD-8 registrations. This draft was received as an e-mail attachment on February 8, 2007

COMPANY: HOMS L.L.C.
P.O. Box 724
Clayton Center
Clayton, N.C. 27520

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
[contact information as per letterhead]

PRODUCTS: Bio-UD-Lotion [82669-R] and Bio-UD-8 Spray [82669-E]

Deficiencies:

- 1) *"Please verify that the test material cited in the study is the actual formulation submitted to support the registration containing 7.75 % w/w methyl nonyl ketone (or 2-undecanone) as active ingredient."*

Response:

There is no way of knowing to which efficacy study your referring, however it is immaterial since in all studies, product chemistry, toxicology and efficacy were carried out with formulations containing 7.75% 2-undecanone, and furthermore these are the formulations for which registration is being sought. So by this statement I am verifying that Bio-UD-8 Lotion [82669-R] and Bio-UD-8 Spray [82669-E]:

- a) are the products for which registration is sought
- b) contain 7.75% w/w 2-undecanone as the nominal concentration of active ingredient
- c) are formulations which have been tested in the studies detailed in the volume identified as MRID 46783509.

This information was previous given to you, in an e-mail dated January 24, 2007 and titled HOMS Bio-UD-Efficacy Studies, a copy of this c-mail is attached to this letter.

Raderio Wilkins
February 13, 2007
Page 2.

- 2] *"The product performance data does not support the proposed labeling claim 'that the product protects against mosquitoes for 4.5 to 6 hours' The products tested contain dermatone and 8% undecanone. It is uncertain whether the test material was the actual product submitted for registration."*

Response

Taking the second part of the statement first, this has been previously addressed, firstly on page 6 of 24 in Volume 82669-RESPONSE-1 submitted to BPPD on October 16 2006, and again in an e-mail dated January 24, 2007. In these latter documents it is explained that previously in various documents the products for which registration is being sought were referred to as Bio-UD-8, Code UD-8, Tropical HOMS Bio-UD-8 and BioBlock and BioBlock with 2-undecanone. HOMS agreed that this was confusing and agreed to refer in all future correspondence etc., only to Bio-UD-8 Lotion and Bio-UD-8 Spray as the products for which registration is being sought. It should be noted here registration is not being sought for any product containing Dermatone. In one of the tests one of the test articles was named BioBlock with Dermatone; in another test a Bio-UD-30 Spray was tested, these were merely test articles for which data are given however these particular data are not being relied upon to substantiate the claims of repellency nor the duration of the repellency.

That the claims duration has not been demonstrated is patently not true. Regarding the mosquitoes for example I refer you to Tables 1, 2 and 3 (pages 23-26 in MRID 46783509). In particular this is clearly expressed in the summary table on page 26. Regarding the ticks, in two studies repellency was shown for 2 to 2.5 hours. In a third test (against American Dog Ticks) filter paper to which Bio-UD-8 had been applied was repellent to the ticks more than 9 hours after the application. However, in the labels being sought the tick claims is one of repellency with no duration stated, and the data unequivocally demonstrates repellency, and even greater repellency than an EPA registered product containing 7% DEET

Previously submitted to BPPD was the data evaluation report of CDPR who have approved these products for registration. In the report submitted to you was the efficacy reviews by Dr. Ghazanfari. Considering the public pronouncements from the EPA regarding sharing and acceptance of data reviews, etc. with both CDPR and PMRA we are interesting in knowing whether the EPA efficacy reviewer was ever shown the submitted evaluation report, and if so was there any communication with Dr. Ghazanfari? If the BPPD reviewer still believes that both the mosquito and tick claims have not been substantiated (not withstanding our rebuttals and the CDPR evaluation report) then the scientists involved are willing to meet with the reviewer and other BPPD staff to explain their results and discuss why they believe the studies support the claims. This however would have to be done on a time frame that does not result in BPPD wanting to yet again "renegotiate the PRIA date."

I have today reviewed again the draft label claims and I believe that we have substantiated each and every one of them. However, the claim "Repels ticks and other arthropods" we would be willing to remove from the label at this time as being too general although mosquitoes are arthropods, and come back in later as part of a label amendment.

- 3] *"The labeling claim for repellency against ticks and other arthropods is unacceptable; the experimental design lacked replications. The same ticks were tested for consecutive periods and data was not statistically analyzed. It is uncertain whether the formulations tested were indeed the actual product proposed for registration."*

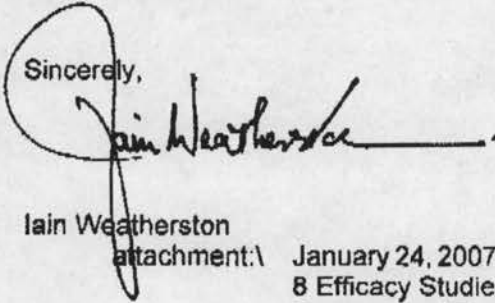
Raderrio Wilkins
February 13, 2007
Page 3.

Response

In response to this point please review the attached response prepared for HOMS by the UNC scientists that conducted the studies.

Raderrio, these responses fully address the points in your February 8, 2007 e-mail, the responses have been delivered in the time-frame I indicated and hence we look forward to an approval by March 26, 2007.

Sincerely,



Iain Weatherston

attachment:\

January 24, 2007 E-mail I. Weatherston to Raderrio Wilkins "HOMS Bio-UD-8 Efficacy Studies."
Response of Dr. R. Michael Roe

Iain Weatherston

From: "Iain Weatherston" <jazkatz@qwest.net>
To: <Wilkins.Raderrio@epamail.epa.gov>
Sent: Wednesday, January 24, 2007 1:25 PM
Subject: HOMS Bio-UD-8 Efficacy Studies

Raderrio:

Following up on your comment today that you were of the opinion that Clara indicated the products used by HOMS in the product performance studies were not the same as the products for which we are seeking approval. If your understanding of her comments is correct the she (Clara) is wrong. Her confusion may have been caused because as was pointed in the deficiency letter dated September 13 page 2 point 4 we had in the various tests and hence the reports used several different names for the products eg Code UD-8, Bio-UD-8 Tropical, HOMS Bio-UD-8 and BioBlock. In our response (Volume 82669-RESPONSE-1) submitted October 16, 2006 we admitted (Page 6 of 24) to using several names and agreed to from then on only use Bio-UD-8 Lotion and Bio-UD-8 Spray.

On behalf of HOMS I contend that in all of tests against mosquitoes and ticks used the two products for which we seek approval. If you review the efficacy volume [MRID 46783509] you will see that there are essentially six tests.

#1	pages 6-9	Bio-UD-8 lotion	mosquitoes
#2	pages 11-14	Bio-UD-8 lotion	mosquitoes
#3	pages 15-27	BioBlock with 2-undecanone (the spray)	mosquitoes
#4	pages 28-39	Bio-UD-8 spray	ticks
#5	pages 40-64	Bio-UD-8 spray and lotion	ticks
#6	page 65	Bio-Ud-8 lotion	mosquitoes

I believe that at this stage we have properly addressed all of the deficiencies and look forward to an expedited approval in the very near future.

Best regards,
Iain

Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 North 156th Drive,
Goodyear, AZ 85338
623-535-4060 [T]
jazkatz@qwest.net

2/10/2007

148

Insect Toxicology & Biotechnology 919-264-4317
1895 Woodards Dairy Road
Middlesex, North Carolina 27657

InTox Biotech

February 8, 2007

TO: HOMS, LLC

FROM: Dr. R. Michael Roe, Ph.D.
President of InTox Biotech

On Feb. 8, 2007, HOMS provided in an email an EPA Excerpt which stated the following: "The labeling claim for repellency against ticks and other arthropods is unacceptable: the experimental design lacked replications. The same ticks were tested for consecutive periods and data was not statistically analyzed. It is uncertain whether the formulations tested were indeed the actual product proposed for registration."

The following is my response to this review of my data and report:

1. EPA excerpt, "the experimental design lacked replications."

Roe response: **Report on American dog tick;** page 2, lines 15-16, "No ticks used were ever re-used except when a control and treatment test was conducted on the same day." Pages 11-12 (Table 5) is the results for replicate 1 for Bio-UD-8-lotion conducted on May 12, 2005; pages 13-14 (Table 6) is the results for replicate 2 for Bio-UD-8-lotion conducted on September 27, 2005; Pages 15-16 (Table 7) is the results for replicate 3 for Bio-UD-8-lotion conducted on September 28, 2005. **Report on deer tick;** Page 1, lines 3-4, "BioUD-8 on human skin was shown in replicated experiments to be repellent to the deer tick...." Page 2, lines 8-9, "No ticks used were ever re-used except when a control and treatment test was conducted on the same day." Pages 4-6 (Table 1) is the results for replicate 1 for Bio-UD-8-spray conducted on October 12, 2005; Pages 7-9 (Table 2) is the results for replicate 2 for Bio-UD-8 spray conducted on October 13, 2005; Pages 10-12 (Table 3) is the results for replicate 3 for Bio-UD-8-spray conducted on October 13, 2005.

In summary, in both tick reports each replicate of the original data collected is presented in separate tables; this must be considered as true replicated data because in the description of the methods for each report, it is stated that ticks were not reused for these experiments.

2. EPA excerpt, "The same ticks were tested for consecutive periods"

Roc response: As explain in item 1, the same ticks were not used between replicates. It is correct that the same ticks were used within each replicate to obtain a time course of the tick response after its first exposure to the repellent after 2 h on the skin of the human subject. A time course is required in a behavioral test because an animal's response to a repellent is not immediate; time is needed for the tick to respond to the repellent and make its choice. A single time point measurement is not appropriate because the ticks could be moving randomly and only a snapshot in time could provide incorrect information. Note that all of the responses in the time courses obtained except for the moment the ticks were exposed to the skin show repellency (a discussion of statistics to validate this conclusion will follow under item 3).

3. EPA excerpt, "data was not statistically analyzed"

Roc response: The results for both the American dog tick and deer tick were clearly repellent for the entire time course for all replicates. For example, in the case of the deer tick, the repellency for the three treatment replicates 15 min after being exposed to the treated skin was 100% with no variation between replicates; in case of the American dog tick for the three treatment replicates, the repellency after 15 min was 89% with almost no variability between replicates. Using the Proc Freq statement and an exact binomial test procedure in SAS/STAT (SAS, 2001. SAS/STAT Software Version 802. SAS Institute Inc., Cary, NC, USA), repellency for the deer tick for the three treatment replicates is significant with a P value of 0.0000038; for the American dog tick for the three treatment replicates, the P value is 0.00066.

4. EPA excerpt, "It is uncertain whether the formulations tested were indeed the actual product proposed for registration."

Roc response: In item 1 above, the location of each replicate of data for the American dog tick and deer tick in my reports are given. Each replicate is given in a separate table as also identified in item 1. In the title of each of these tables, the repellent is identified as Bio-UD-8 lotion for the American dog tick or Bio-UD-8-spray for the deer tick.

I hope this information answers your questions. Please feel free to contact me (919-280-2319; michael_roc@ncsu.edu) if you need any further information.



Iain Weatherston
<jazkatz@qwest.net>
02/11/2007 01:52 PM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc Linda Hollis/DC/USEPA/US@EPA
bcc
Subject HOMES-BIO-UD-8 RESPONSE TO FEBRUARY 8, 2007
DEFICIENCY E-MAIL

History: This message has been forwarded.

Raderrio:

Attached are three documents which comprise our response to your February 8, 2007 deficiency e-mail. These documents form a six page response and address all the points raised in the February 8 e-mail. This has been delivered to you within the time frame I indicated so we look forward to an expeditious approval of both products.

I attempted to fax this response to you several times during Saturday February 10 and again on Sunday February 11 however the fax number 703-305-0118 was not operating. I will try again on Monday to fax the package to you since you will then have a signed letter.

Iain Weatherston

Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
4061 N. 156th Drive,
Goodyear, AZ 85338
623-535-4060 [T]



jazkatz@qwest.net TickResponse.pdf Jan24 e-mail.pdf EFFRESPONSELETTER.pdf

Raderrio
Wilkins/DC/USEPA/US
02/08/2007 12:23 PM

To Iain Weatherston <jazkatz@qwest.net>
cc
bcc
Subject Re: HOMS 2-UNDECANONE PRODUCTS

*This was an internal
letter (the official
letter is following)
MWR*

Dear Iain Weatherston, Ph.D.:

The product performance data for a Biopesticide registration referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been reviewed by BPPD and found to be unacceptable for the following reasons:

1. Please verify that the test material cited in the study is the actual formulation submitted to support this registration, containing 7.75 % w/w methyl nonyl ketone (or 2-undecanone) as its active ingredient.
2. The product performance data does not support the proposed labeling claim, "that the product protects against mosquitoes and ticks for 4.5 to 6 hours". The products tested contained permethrin and 8% undecanone. It is uncertain whether the test material used in the study was the actual product submitted for registration.
3. The labeling claim for repellency against ticks and other arthropods is unacceptable: the experimental design lacked replications. The same ticks were tested for consecutive periods and data was not statistically analyzed. It is uncertain whether the formulations tested were indeed the actual product proposed for registration.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B65) of five months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there are forty-two days remaining before the PRIA decision date of March 26, 2007 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision.

The PRIA due date of March 26, 2007 is contingent on the assumption that HOMSS L.L.C. will submit the required data to BPPD on or before February 13, 2007. Therefore, you may renegotiate the due date or withdraw the application and resubmit when you can address the deficiencies or the Agency will issue a cannot grant letter under PRIA on or about March 26, 2007. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information within 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately or within five (5) days from the date of

this letter at (703) 308-1259 with your response.

Sincerely,
Raderrio Wilkins
Biochemical Pesticide Branch

Iain Weatherston <jazkatz@qwest.net>



Iain Weatherston
<jazkatz@qwest.net>
02/08/2007 11:55 AM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc

Subject HOMS 2-UNDECANONE PRODUCTS

Bio-UD8 Spray [82669-E] and Bio-UD8 Lotion

[82669-R]

Raderrio:

Following on from our conversation this morning, this e-mail authorizes you to scan in and transmit to me electronically the most recent deficiencies noted by the reviewer on the product performance data for the above products.. If the responses to be deficiencies can be communicated back to the you electronically, then you will have them no later than Monday February 13, if on the other hand if some of the information needs to be sent to you in hard copy you will have it on the morning of Tuesday February 14, by FedEx.

Regards,
Iain



Iain Weatherston
<jazkatz@qwest.net>
02/08/2007 11:55 AM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc
bcc
Subject HOMS 2-UNDECANONE PRODUCTS

Bio-UD8 Spray [82669-E] and Bio-UD8 Lotion

[82669-R]

Raderrio:

Following on from our conversation this morning, this e-mail authorizes you to scan in and transmit to me electronically the most recent deficiencies noted by the reviewer on the product performance data for the above products.. If the responses to be deficiencies can be communicated back to the you electronically, then you will have them no later than Monday February 13, if on the other hand if some of the information needs to be sent to you in hard copy you will have it on the morning of Tuesday February 14, by FedEx.

Regards,
Iain



Iain Weatherston
<jazkatz@qwest.net>
02/03/2007 02:23 PM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc
Subject Re: HOMS-Bio-UD-8

2/03/07
See attached
pages (email message
was separated during
printing)
R. Wallin

Cont.
2/03/07
2:23 pm

Linda:

Thank you for the message, I will await a conversation with Raderrio.

Iain

----- Original Message -----

From: <Hollis.Linda@epamail.epa.gov>

To: "Iain Weatherston" <jazkatz@qwest.net>

Cc: <Wilkins.Raderrio@epamail.epa.gov>

Sent: Friday, February 02, 2007 5:56 PM

Subject: Re: HOMS-Bio-UD-8

> Iain: Raderrio has been working diligently on these submissions and as
> you have noted, I am also happy with his work and communications with
> you thus far. Please allow Raderrio the opportunity to respond to your
> request as he is out of the office today and will return next week. I
> can tell you however, that unless the Agency completes its scientific
> and administrative reviews early, you can expect that we will make our
> regulatory decision by March 26th. The 3 month time was the allotted
> time necessary for BPPD to conduct review and make a regulatory
> decision.

>
> Raderrio will repond to your email next week.
> to -----\Sent by EPA Wireless E-Mail Services.

>
> From: Janet Andersen
> Sent: 02/02/2007 05:56 PM
> To: Iain Weatherston <jazkatz@qwest.net>
> Cc: Linda Hollis; Raderrio Wilkins
> Subject: Re: HOMS-Bio-UD-8

> You need to work this first through Raderrio and then if that is not
> satifactory, through Linda before you bring this to me. I am sure
> Raderrio can help you.

>
>
> Iain Weatherston
> <jazkatz@qwest.n
> et>
>
> 02/01/2007 06:20
> PM
>
> Janet Andersen/DC/USEPA/US@EPA
> Raderrio Wilkins/DC/USEPA/US@EPA,
> Linda Hollis/DC/USEPA/US@EPA
> Subject
> HOMS-Bio-UD-8

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>
> Janet;
> I have had Allen Jones, the President of Homs L.L.C. on the phone every
> day for the last five questioning as to when he can expect to get
> approval for both of his mosquito and tick repellent products Bio-UD-*
> Lotion and Bio-UD Spray [82669-R & E]. The last date renegotiated

> following a January 10, 2007 conversation with Raderrio was March 26,
> this delay from January 4 to March 26 was predicated on their being
> product chemistry deficiencies. When the January 10 DER was received it
> indicated that all previous product chemistry deficiencies had been
> satisfactorily addressed and the only outstanding product chemistry
> issue was:

>

> "The additionally submitted data upgraded the application for
> registration of Bio-UD-8 Lotion (EPA Reg No. 82669-R) and Bio-UD-8 Spray
> (EPA 82669-E) to acceptable, the storage stability is pending, provided
> the additional information about the formulation process of the lotion
> is moved from the Administrative Volume 82669-Response-1, p 6 of 24 to
> MRID 469619-02. It is not acceptable to refer to the CSF for
> recalculation of batches (please refer to BPPD's review dated 9/13/06)."

>

> These product deficiencies it is felt by HOMS does not warrant a delay
> of two and a half months.

>

> Attached to the DER was a marked up draft label for each product, on
> review I did not agree with some of the requests to modify or remove
> claims which referred to specific diseases. Three days after the call on
> January 10 and receiving the DER/labels all points were completely
> addressed in 15 page response (by both e-mail and fax).

> Next on January 16 Raderrio called to discuss whether the mosquitoes and
> ticks in the HOMS efficacy studies were actually the vectors of the
> named diseases. As I indicated to him, later that morning literature
> showing that the species used in the HOMS tests were actually species
> known to be vectors of the diseases mentioned in the claims. At this
> time I also sent in a copy of the CDPR registration evaluation for
> these products since I believe that both agencies accept data reviews of
> the other.

> Then on January 24, 2007 Raderrio mentioned that Clara Fuentes had
> indicated that the HOMS field studies were not carried out with the same
> products for which we are seeking approval. Again this was addressed in
> a matter of hours.

> Yesterday I left a voice mail requesting an update since Mr. Jones was
> asking me to contact you. I told him that if I did not hear from
> Raderrio today I would write to you, hence the letter now, but this is
> not to be construed that I am unhappy with Raderrio. Mr. Jones is
> unhappy with the system and points out that there is no written
> communication from the Agency indicating that the new PRIA date is Match
> 26, it is written but that is in e-mails from me to Raderrio.

> So, could you please give me a status of the applications and let me
> know whether it is possible to have the approval before March 26, 2007.

> Thank you

> Iain

>

>

>

>

>

>

Raderrio Wilkins/DC/USEPA/US

01/22/2007 12:23 PM

To Iain Weatherston <jazkatz@qwest.net>

cc

bcc

Subject Re: Pria Renegotiation Approval


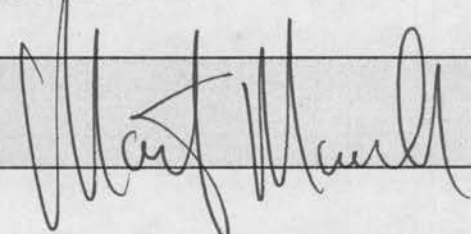
Subject: Request for a new PRIA date of March 26, 2007
BIO-UD-8 Spray and BIO-UD-8 Lotion
EPA File Symbol: 82669-E and 82669-R
Your submission of December 4, 2005

Dear Iain Weatherston, Ph.D.:

The Biopesticides and Pollution Prevention Division reviewed your request for a sixty day (60) extension to give you time to address the deficiencies identified in the product chemistry study. The new PRIA date has been renegotiated from January 24, 2007 to March 26, 2007. The PRIA due date of March 26, 2007 is contingent on the assumption that HOMSS L.L.C. will submit the required data to BPPD on or before February 13, 2007.

Should you have questions concerning this action, please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product at (703) 308-1259.

Sincerely,
Raderrio Wilkins
Biochemical Pesticide Branch

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 366018	Registration#: 82669-E	Petition #: N/A
Fee Category: B65	PRIA Decision Time Frame: 3 months	
Submitted by: Raderrio Wilkins	Branch: BPB	Date: January 11, 2007
Company: HOMS LLC c/o Technologies Science Group Inc.		
Original Due Date: October 9, 2006	Proposed New Due Date: March 26, 2007	
Previous Negotiated Due Dates: January 24, 2007		
Is the "Fix" in-house? Yes. The registrant agreed to submit the required data to the Agency on or before January 26, 2007.		If not, date "Fix" expected:
Issue (describe in detail): The proposed use of these products as a mosquito and tick repellents is new for the Active ingredient. The registrant is relying on data submitted to register the product BIO-UD-8 Spray (EPA File Symbol 82669-E) to support the registration of BIO_UD-8 Lotion (EPA File Symbol 82669-R). The application for registration of BIO-UD-8 (EPA File Symbol 82669-E), is not acceptable for the following reasons: (1) the registrant must provide specific data on the formulation process and the amounts of the ingredients used to produce a typical batch; (2) revise label to address labeling deficiencies; and (3) revise CSF to address deficiencies.		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company's agent (Ian Weatherston) was contacted about the necessity of negotiating their PRIA due date of January 24, 2007 to allow his client time to address the deficiencies identified in their product chemistry study. On January 10, 2007, BPPD received an e-mail asking that the PRIA due date be extended for sixty days to March 26, 2007. This extension is contingent on the assumption that HOMS LLC will resubmit the required data on or before January 26, 2007.		
Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases III – V, which is equivalent to 3 months. BPPD believes a sixty (60) day extension would allow the registrant time to address the deficiencies associated with the label and product chemistry.		
Other Comments: This is HOMS LLC second request for a PRIA renegotiation.		
Approve: 	Disapprove:	
If disapproved, action to be taken:		
OD or DOD Signature: 	Date: 1-19-07	

October 26, 2006



Iain Weatherston
<jazkatz@qwest.net>

01/10/2007 03:49 PM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc

bcc

Subject Homs Bio UD-8 Products

Bio-UD8 Spray [82669-E] and Bio-UD8 Lotion [82669-R]

Dear Raderrio:

Subsequent to our conversation of a few moments ago I understand that there are a few product chemistry deficiencies with the applications to register the BIOD-8 spray and lotion.. In order for me to address these deficiencies, and on behalf of HOMS L.L.C. I accept the change in the PRIA date of January 24, 2007 to March 26, 2007. Also once I receive the deficiency letter, I will call you tomorrow to let you know how I plan on responding.

Regards,
Iain

Iain Weatherston, Ph.D.
Technology Sciences Group Inc.,
4061 North 156th Drive
Goodyear, AZ 85338
623-535-4060 [T]
jazkatz@qwest.net.

Receipt for Section 3

S: 800434

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Pending Product Amendment

Billable: ☐ Yes ☒ No

Company: 82669 HOMS, L.L.C.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 82669-E Product Name: BIO-UD-8 SPRAY

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 18-Oct-2006

ie

OPP Rec'd Date: 19-Oct-2006

ie

Front End Date: 19-Oct-2006

ie

Risk Manager Send Date: 19-Oct-2006

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

response to EPA letter of 9/13/06

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐


Signature Date:

Receipt Content

Study

AIO-Rodriguez
11/16/07
adh

Linda Hollis/DC/USEPA/US
10/19/2006 10:15 AM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc Driss Benmhend/DC/USEPA/US@EPA
bcc
Subject Re: Please notify me upon receipt of Bio-UD-8 Spray and
Bio-UD-8 Lotion
82669-R and 82669-E. 

Noted, but be advised that it takes days to process before we see it

Linda A. Hollis
Biologist
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (ph)

Raderrio Wilkins/DC/USEPA/US

Raderrio
Wilkins/DC/USEPA/US
10/19/2006 10:03 AM

To Linda Hollis/DC/USEPA/US@EPA
cc Driss Benmhend/DC/USEPA/US@EPA
Subject Please notify me upon receipt of Bio-UD-8 Spray and
Bio-UD-8 Lotion
82669-R and 82669-E.

Greetings Everyone,

Please notify me upon receipt of Bio-UD-8 Spray and Bio-UD-8 Lotion 82669-R and 82669-E. The attached e-mail is a response to the Agency's renegotiation agreement that was contingent on the assumption HOMs LLC would submit the required data on or before October 10, 2006. The PRIA due date is January 24, 2007.

Raderrio

----- Forwarded by Raderrio Wilkins/DC/USEPA/US on 10/19/2006 09:42 AM -----



Iain Weatherston
<jazkatz@qwest.net>
10/18/2006 06:10 PM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc Allen <allenj@homs.com>
Subject RESPONSE TO EPA LETTER DATED SEPTEMBER
13.....

HOMS L.L.C. Bio-UD-8 Spray and Bio-UD-8 Lotion [82669-r and 82669-E]

Raderrio:

I have put into FedEx a three volume response to the EPA letter of September 13, 2006, subsequent telephone conversations and your e-mail dated October 3, 2006. It should arrive at the Agency tomorrow, Thursday October 19, 2006.

I have attached the transmittal document for your information.

Regards,



Iain RESPONSE-TD.wpd RESPONSE-TD.pdf

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 10 2006

HOMS L.L.C.
c/o Iain Weatherston, Ph.D.
P.O. Box 724
Clayton, NC 27520

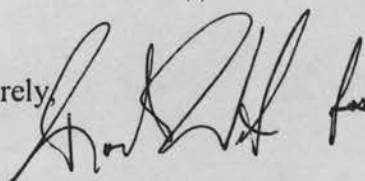
Subject: Request for a new PRIA date of January 24, 2007
BIO-UD-8 Spray and BIO-UD-8 Lotion
EPA File Symbol: 82669-E and 82669-R
Your submission of December 4, 2005

Dear Iain Weatherston, Ph.D.:

The Biopesticides and Pollution Prevention Division reviewed your request for a one hundred and five day (105) extension to give you time to address the deficiencies identified in the Agency's letter (dated September 13, 2005). The new PRIA date has been renegotiated to January 24, 2007. This extension is contingent on the assumption that HOMSS L.L.C. will submit the required data on or before October 10, 2006.

Should you have questions concerning this action, please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product at (703) 308-1259.

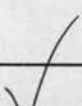
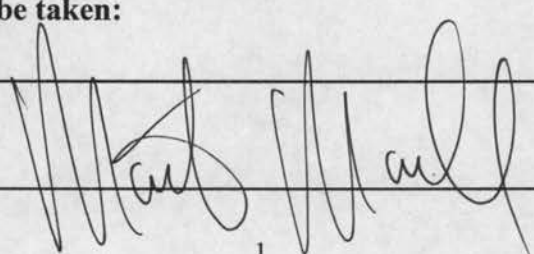
Sincerely,




Janet Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Divisions (7511C)

CONCURRENCES

SYMBOL	7511P	7511P					
SURNAME	Raderrio Wilkins	Harris					
DATE	10/10/06	10/10/06					

<div style="text-align: center;"> Recommendation of Division Directors Negotiated Due Dates </div>		
Decision#: 33018 366018 and 365798		Registration#: 82669-E and 82669-R
Fee Category: B65		PRIA Decision Time Frame: 3 months
Submitted by: Raderrio Wilkins	Branch: BPB	Date: September 26, 2006
Company: HOMS L.L.C c/o Technologies Science Group Inc.		
Original Due Date: October 9, 2006		Proposed New Due Date: January 24, 2007
Previous Negotiated Due Dates: None		
Issue (describe in detail): <p>The proposed use of these products as a mosquito and tick repellents is new for the Active ingredient. The registrant is relying on data submitted to register the product BIO-UD-8 Spray (EPA File Symbol 82669-E) to support the registration of BIO-UD-8 Lotion (EPA File Symbol 82669-R).</p> <p>The application for registration of BIO-UD-8 (EPA File Symbol 82669-E), is not acceptable for the following reasons: (1) the registrant must submit a better waiver rationale for the hazardous properties of the volatile inert ingredients; (2) the waiver requested for immunotoxicity is not in compliance according to OPPTS 880.3550; (3) the products under review are not identified by certificate of analysis in the efficacy studies; and (4) must revise CSF to address deficiencies. The efficacy studies submitted to support this registration used humans in their study</p> <p>The data submitted for the registration of BIO-UD-8 Lotion (EPA File Symbol 82669-R), is not acceptable for the following reasons: (1) the registrant did not provide specific data about the viscosity, specific gravity and pH for the product; and (2) registrant did not provide specific data regarding the formulation process and the amount of ingredients used to produce a typical batch of BIO-UD-8 Lotion.</p>		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): <p>The company's agent was contacted about the necessity to request a negotiated PRIA date and on 9/25/06 BBPD was in receipt of an email asking that the PRIA due date be extended to December 10, 2006. On 9/29/06 the Agency received a second e-mail requesting the PRIA date be extended to January 24, 2007.</p>		
Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases III – V, which is equivalent to 3.5 months. The 105 day extension would allow the registrant time to address the inconsistencies in their data studies.		
Other Comments:		
Approved: 		Disapproved:
If disapproved, action to be taken:		
OD or DOD Signature:  10-4-06		

Raderrio
Wilkins/DC/USEPA/US
10/03/2006 11:57 AM

To: Iain Weatherston <jazkatz@qwest.net>
cc
bcc
Subject: Re: EPA File symbol 82669-E and 82669-R resubmission 

Dear Iain Weatherston, Ph.D:

Per our telephone conversation (dated 10/3/06), here is the regulation that explains why all patch tests must go to the HSRB, but any efficacy studies initiated before April 7, 2006 does not need to go through the board. Your client must comply with 26.1303 by submitting a supplement to each human study they submitted since last April 7th addressing the requirements of this rule. The supplements should be organized to make it easy for BPPD to apply the checklist. I suggest they use the checklist as a table of contents, and show page references in the "comments" column. The supplements should be formatted to meet PR Notice 86-5 requirements, and submitted to the Front End Unit in the customary way, clearly identified as supplements to the previously assigned MRIDs. Until HOMS L.L.C. have done this, their submissions are not complete enough to support the EPA review required by 26.1602(a), whether or not they must also go to the HSRB.

§26.1602 EPA review of completed human research.

(a) When considering data under FIFRA or FFDCA from research involving intentional exposure of humans, EPA shall review the material submitted under §26.1303 and other available, relevant information and document its conclusions regarding the scientific and ethical conduct of the research.

(b) EPA shall submit its review of data from human research covered by subpart Q, together with the available supporting materials, to the Human Studies Review Board if EPA decides to rely on the data and:

- (1) The data are derived from research initiated after April 7, 2006, or
- (2) The data are derived from research initiated before April 7, 2006, and the research was conducted for the purpose of identifying or measuring a toxic effect.

26.1602(b)(1) requires that *ALL* intentional exposure studies *initiated after* the effective date of the rule (April 7) must go to the Board, including efficacy studies and exposure studies as well as toxicity studies. Subsection (b)(2) provides that for older studies--i.e., those *initiated before* the effective date of the new rule--only toxicity studies, including patch tests for irritancy or sensitization, are required to go to the Board. (EPA has the discretion to refer other studies to the Board as well, but that's irrelevant to your case.)

Here's the regulatory requirement for documenting ethical conduct again:

§26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

- (a) Copies of all of the records relevant to the research specified by §26.1115(a) to be prepared and maintained by an IRB.

- (b) Copies of all of the records relevant to the information identified in §26.1125(a) through (f).
- (c) Copies of sample records used to document informed consent as specified by §26.1117, but not identifying any subjects of the research.
- (d) If any of the information listed in paragraphs (a) through (c) of this section is not provided, the person shall describe the efforts made to obtain the information.

Summarized requirement checklist--meant to be applied to each study:



26.1303 requirements.doc

26.1303 requires documentation of ethical conduct for *ALL* human studies *submitted after* the effective date of the rule, regardless of when they were initiated, or whether they involved intentional exposure, or whether they are toxicity studies. 26.1303(d) allows for the possibility that some of the required documentation may not be available, but with that exception, all the elements identified in 1303 are required for each study submitted.

Sincerely,
Raderrio Wilkins
Biochemical Pesticide Branch
(703) 308-1259

Iain Weatherston <jazkatz@qwest.net>



Iain Weatherston
<jazkatz@qwest.net>
09/29/2006 12:05 PM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc ajones@homs.com
Subject PRIA DATE

EPA File Symbols: 82669-R and 82669-E

Raderrio:

Following our conversation this morning, concerning another new PRIA date of January 24, 2007, HOMS will accept this date, will however since the response to the deficiencies noted in Ms. Simeonova's evaluation report be in the Agency on or before October 10, 2006, with October 5 being the primary target date..

Regards,
Iain

Iain Weatherston
Technology Sciences Group Inc.
40-61 North 156th Drive
Goodyear, AZ 85338
623-535-4060 [T]
jazkatz@qwest.net

Registration Details

Company: 82669 HOMES, L.L.C.

Risk Mgr: RM 91 Biologicals & Pollution Prevention Division, PM Team 91

Organization: BPPD / BPB

Current Status: Under Review (15-Mar-2006)

Reg. Number: 82669-E Pesticide Type: Biochemical High Exposure? ☐

Use Type: EP Signal Word: None

Repack: ☐ Yes ☒ No

NPIC Phone: ☐ Yes ☒ No WPS Written Notification: ☐ Yes ☒ No

Related Products ☒ Restricted Use ☒ Reg. Expiration Date ☒

Use Patterns ☒ Transfer History ☒ Toxicology ☒ Mode Of Action ☒ FR Notice ☒ Receipts ☒

Product Name ☒ **Ingredient** ☒ Formulation Property ☒ Pesticide Category ☒ Permitted State ☒

PC Code	CAS Number	Ingredient Name	Percent Wt Value
044102	112-12-9	Methyl nonyl ketone	7.75

WPS-PPE

Label Image

Container Info

Tracking

Status

Sites/Pests

CSF

Data Requirements

Generate Rqmts

Inert Ingredients

Nasrin B... WordPer... EPA-O... Desktop My Computer 2:58 PM

S792898

B65 - New Fast TRACK TEAM - Driss

(Chris)

~~S792898~~

S792898 - OPPIN will
not let me change ownership
from RD/IRB to BPPD/BPB,
Team 91

LH
5.11.06

ATC
MAY 15 2006

sdh

ATTACHMENT 1

Administrative Material Screening Checklist

Date: 4/25/06

EPA Reg. No. : 82669-E ; Priority code: B-65- non-fast

Active ingredient name: 2-Undecanone

Division RAL assigned (if any): Driss Benmhend

PASS

Admin Materials	Signed		Date	Absent	Comments
	Yes	No			
Form 8570-1	X		4/4/06		-Application is for an new use, re-submission of a product chemistry (illegibility issue) study, for a non-food end use product.
CSF - Completely filled out & original signature (EPA form 8570-4)	X		12/4/05		- Biochemical AI present -No additional brand name listed
<ul style="list-style-type: none"> • inerts cleared? • conventional or antimicrobial actives present in formulation? • accurate information provided for suppliers/source? • csf accurately reflects label? • Additional brand name listed in CSF • note all comments 	y				
Method of Support, if so state which	X		12/4/05		selective
Label					
<ul style="list-style-type: none"> • legible product label? • label accurately reflects csf? • note all comments 	Y				label reflects CSF
Physical address of manufacturer on label	Y				
Data Matrix - Two/one for jacket; one for FOIA (EPA Form 8570-35)	X		8/1/05		yes
<ul style="list-style-type: none"> • supports method of support? • reflects information reported in transmittal document and company cover letter? • note all comments 	X				

Registration Details

Company: 82669 HOMES, L.L.C.

Risk Mgr: RM 91 Biologicals & Pollution Prevention Division, PM Team 91

Organization: BPPD / BPB

Current Status: Under Review (15-Mar-2006)

Reg. Number: 82669-E Pesticide Type: Biochemical High Exposure? ☐

Use Type: EP Signal Word: None

Repack: ☐ Yes ☒ No

NPIC Phone: ☐ Yes ☒ No WPS Written Notification: ☐ Yes ☒ No

Related Products Restricted Use Reg. Expiration Date

Use Patterns Transfer History Toxicology Mode Of Action FR Notice Receipts

Product Name **Ingredient** Formulation Property Pesticide Category Permitted State

PC Code	CAS Number	Ingredient Name	Percent Wt Value
044102	112-12-9	Methyl nonyl ketone	7.75

WPS-PPE

Label Image

Container Info

Tracking

Status

Sites/Pests

CSF

Data Requirements

Generate Rqmts

Inert Ingredients

Nasrin B... WordPer... EPA-O... Desktop My Computer 2:58 PM

S792898

B65 - New Fast TRACK TEAM - Dress

(Chris)

~~S792898~~

S792898 - OPPIN will not let me change ownership from RD/IRB to BPPD/BPB, Team 91

LH
5.11.06

ATC
MAY 15 2006
sdh

Admin Materials	Signed	Date	Absent	Comments
Formulator's exemption form (EPA form 8570-27)	X	12/4/05		2-undecanone EPA Reg.# [REDACTED] Product name [REDACTED]
Transmittal letters <ul style="list-style-type: none"> accurately reflects what is reported on data matrix? note all comments 	X	4/4/06		
Petition/amended petition if food tolerance or exemption/amended food tolerance or exemption <ul style="list-style-type: none"> petition# assigned? petition jacket included? petition complete with sections A-G? note all comments - if there is not evidence of a petition # assigned and sect. A-G not present, package fails.			X	not applicable, non food, feed
FR template if food tolerance or exemption/amended food tolerance or exemption <ul style="list-style-type: none"> notice of filing template (disk) included? note all comments - a NOF must be present to establish a new tolerance exemption. Amendments to an existing tol. petition may be Agency initiated in which case a NOF would not expected to be present. (If unsure, check with branch team leader) component in the formulation not cleared food use 				
Certification with Respect to Citation of Data Form (EPA Form 8570-34) - if required	X	12/4/05		selective method
Minutes on data requirements (pre-registration meeting)				

Admin Materials	Signed		Date	Absent	Comments
Active ingredient # (i.e. Chemical PC code) <ul style="list-style-type: none"> more than one active? are all actives housed in BPPD? 					Single active ingredients housed in BPPD PCC : 044102
Jacket from EPA Identifying Symbol					82669-E
Are MRIDS assigned? (State Yes/No in comments)					Y
Background Experimental Use Permit information, if applicable <ul style="list-style-type: none"> request for temporary tol. exempt, tol. exemption or numeric tolerance? note all comments - refer to petition and fr section for criteria.				No	NA

Additional Comments:

CHECKLIST FOR DATA PACKAGE SCIENCE SCREEN

Active Ingredients and PC codes: 2-undecanone ; 044102

Product Name: Bio-UD8-SPRAY

EPA Reg. No/File Symbol: 82669-E

Petition # (if applicable):

(Circle or Check Appropriate Boxes)

Product Type				
Biochemical, Microbial, or PIP	<input type="checkbox"/>	B	M	P
Food Use	<input type="checkbox"/>	N		
Straight-chain Lepidopteran Pheromone (Biochemical Only)	<input type="checkbox"/>	N		
New Active Ingredient	<input type="checkbox"/>	N		
3 Registration	<input type="checkbox"/>	Y		
Experimental Use Permit	<input type="checkbox"/>	N		
IR-4 Submission	<input type="checkbox"/>	N		
Methyl Bromide Alternative	<input type="checkbox"/>	N		
Reduced Risk Product	<input type="checkbox"/>	Y		
Product Specific Information				
Data Requirement	TGAI	MP	EP	
Product Label			Y	
Product Chemistry				
			Y	complete
Product Identity & Composition			Y	Study submitted in 468049-01
Manufacturing Process			Y	Study submitted in 468049-01
Description of the Formation of Impurities				Study submitted in 468049-01
Preliminary Analysis				
Certified Limits			Y	Study submitted in 468049-01
Analytical Methods			Y	Study submitted in 468049-01
Physical/Chemical Properties (as shown in 40 CFR 158.190 Table)				Study submitted in MRID# 487835-02
Tier I Toxicity (If no study, indicate in Comments if waiver submitted)				

Acute Oral				Study submitted in MRID#467835-03
Acute Dermal				Study submitted in MRID#467835-04
Acute Inhalation				Study submitted in MRID#82669-R-7
I.C., I.P., I.V. Injection (Microbial only)				
Primary Dermal Irritation				Study submitted in MRID#487836-06
Primary Eye Irritation				Study submitted in MRID#467835-05
Hypersensitivity (Conditionally required)				Study submitted in MRID#467835-08
Hypersensitivity Incidents (Conditionally required)				Study submitted in MRID#467835-08
Genotoxicity Studies (Biochemical only)				
Immune Response				Waiver request submitted in MRID#467835-07
Issue Culture (Microbial only)				
90-day Feeding (Biochemical only)				
90-day Dermal (Biochemical only)				Study (waiver request) submitted in 467835-07
90-day Inhalation (Biochemical only)				
Teratogenicity/developmental toxicity (Biochemical only)				
Tier I Non-Target Organisms (If no study, indicate in Comments if waiver submitted)				
in Acute Oral				
Avian Acute Dietary				
Freshwater Fish LC50				
Freshwater Invertebrate LC50				
Non-target Plants				
Non-Target Insects				
Honeybee Testing (Microbials only)				na
Other Studies [As required by product specific data requirements(e.g. efficacy, residues)]				
Efficacy study				Study submitted in MRID# 467835-09

Science Screen Comment Form

Active Ingredients and PC codes: 2-undecanone; 044102

Product Name: Bio-UD8-SPRAY

EPA Reg. No/File Symbol: 82889-E

RAL: Driss Benmhend

Status: PASS

THIS FORM DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Product Chemistry:

Data requirement is addressed by submitted studies appears to be adequate

Efficacy:

Data requirement is addressed by submitted studies and waiver request seems to be adequate.

Non-target Organisms/ Environmental Fate:

not present, may be because of use on the skin not to contaminate environment or non-target organism?

Product Performance (Efficacy):

Data requirement is addressed by submitted studies seems to be adequate.

Residue:

not present, not required (no food or feed use)

Other non guideline or supplemental information:

Comments/Recommendations:

This is a re-submission with replaced pages of a product chemistry study with new use (with supporting data).

BPPD SCREEN PACKAGE

BPPD FRONT END: BPB/MPB: Team Leader: Hollis

Pria Code/Action Code: B65 Team/RAL: B65-DRIS

Product Name: B10-UD-8 SPRAY New Use

EPA ID No.: 82669-E

Active Ingredient(s): 2-undecanone

☐ Food ☒ New Submission
☒ Non Food ☐ Resubmission

} See RED
2-undecanone June 1995

Date In BPPD: 4-11-06

Date To Screen: 4-20-06

~~however, the RED does not support human domestic use~~

Date Expected From Screen: (10 days from date in): 4/28/06 WA# 62

Nasrin Begum: Nasrin Begum Act. Hours 4 Return to BPPD: 4/25/06

Received Date from Contactor: 4/25/06 Blanco

SCREEN PACKAGE NOTES:

Pre- Reg Meetings attached? ☐ Yes ☐ No

Submission complies with all applicable areas of checklists? Indicate in detail on checklists forms when returned.

Additional Comments per Team Leader or Screener:

SCREEN STATUS

Administrative: ☒ Pass ☐ Fail

Scientific: ☒ Pass ☐ Fail

MEMORANDUM

DATE: 4/13/06

TO: BPPD, Regulatory Manager

FROM: Information Services Branch, IRSD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted in OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Maureen Sherrill (305-5361) or Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 12, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TECHNOLOGY SCIENCES GROUP
HOMS, L.L.C.
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 07-APR-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3			
S: 792898	Resubmission: <input checked="" type="radio"/> Yes <input type="radio"/> No		<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>
Regulatory Type: Product Registration - Section 3	Fee For Service: <input type="radio"/> Yes <input checked="" type="radio"/> No		
Application Type: New Registration	Billable: <input type="radio"/> Yes <input checked="" type="radio"/> No		
Company: 82669 HOMS, L.L.C.	V		
Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91			
Product #: 82669-E	Product Name: BIO-LD-8 SPRAY		
Override#:			
Me Too Section3:	Me Too Product Name:		
Application Date: 04-Apr-2006	OPP Rec'd Date: 07-Apr-2006	<div>Receipt Content</div> <div>Study</div>	
Front End Date: 11-Apr-2006	Risk Manager Send Date: 11-Apr-2006		
FFS Due Date:	Negotiated Due Date:		
OPP Target Date:			
Fast Track: <input type="checkbox"/>	New Ingredient: <input type="checkbox"/>		
Receipt Description: resubmission following 86-5 rejection			New Ingredient Request Date: New Ingredient Received Date:
Form A: <input type="checkbox"/>	Signature Date:	Form B: <input type="checkbox"/>	Signature Date:

B65- Non Fast Track Team (Driss)

6 month Action

Due 10/9/06

LH
4-19-06

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net

EPA

4 07 06



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division
Ms. Linda Hollis
Biochemicals Branch
U.S. EPA - OPP - BPPD
Crystal Mall #2, 9th Floor
1801 South Bell Street
Arlington, VA 22202

April 4, 2006

SUBJECT: Application to register Bio-UD-8 Spray, a biochemical pest control agent that repels mosquitoes and ticks.

COMPANY: HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

CONTACT: Iain Weatherston
Technology Sciences Group Inc.
[contact information as per letterhead]

PRODUCT: Bio-UD-8 Spray

ACTION: Resubmission of a product chemistry volume in response to a deficiency letter from 86-5.

Dear Linda:

In response to the deficiency letters from front end screen and yourself, dated respectively, March 21, 2006 and March 26, 2006 (copies attached) please find accompanying this letter the original and two copies of:

VOLUME 82669-2 PRODUCT CHEMISTRY

Since the deficiency involved "illegible pages" all in the appendix of MSDS, as many new "virgin" MSDS as possible were obtained, however some of the MSDS which had to be used were copies of faxes, etc., and so those are the "best copies available" but they are all **legible**.

As per our conversation on March 29, 2006, the volume has been reconstituted and since some of the MSDS used have a different number of pages from the ones originally used, the pagination of the new volume differs from that of the original.

In addition to this letter and the three volumes, the package also contains an executed Application for Pesticide Registration (Form EPA 8570-1).

If you have any questions or are desirous of further information please do not hesitate to contact me by phone or by e-mail.

Sincerely,

Iain Weatherston

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-



United States
Environmental Protection Agency
Washington, DC 20460

Registration
Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 82669-?	2. EPA Product Manager De Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HOMS LLC Bio-UD-8 Spray	PM# 99	
5. Name and Address of Applicant (Include ZIP Code) HOMS LLC P.O. Box 724 CLAYTON NC 27520 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 3/26/06	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.) * copies attached
RESUBMISSION OF VOLUME 82669-R-2 (PRODUCT CHEMISTRY) REJECTED BY 86-5 FOR ILLEGIBLE PAGES.
THE VOLUME HAS BEEN RECONSTITUTED USING "VIRGIN" MSDS IF AVAILABLE. WHERE COPIES ARE USED THEY ARE "THE BEST AVAILABLE".

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions E I	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name IAIN WEATHERSTON	Title SENIOR REGULATORY CONSULTANT	Telephone No. (Include Area Code) 623-535-4060	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature IAIN WEATHERSTON	3. Title SENIOR REGULATORY CONSULTANT		
4. Typed Name IAIN WEATHERSTON	5. Date APRIL 4, 2006		

Administrative

Materials

HOMS L.L.C. 826689-R-TD
Page 1 of 1

467836-00

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application to register Bio-UD-8 Spray

3. TRANSMITTAL DATE

March 7, 2006

4. LIST OF SUBMITTED VOLUMES

VOLUME 82669-R-1	ADMINISTRATIVE VOLUME: CORRESPONDENCE, LABEL, APPLICATION & CONFIDENTIAL STATEMENT OF FORMULA
Reject (01) VOLUME 82660-R-2	PRODUCT CHEMISTRY
46783502 VOLUME 82669-R-2S	PRODUCT CHEMISTRY - SUPPLEMENTAL VOLUME
46783503 VOLUME 82669-R-3	ACUTE ORAL TOXICITY [LD50 rat] STUDY
46783504 VOLUME 82669-R-4	ACUTE DERMAL TOXICITY [LD50 rat] STUDY
46783505 VOLUME 82669-R-5	ACUTE EYE IRRITATION STUDY
46783506 VOLUME 82669-R-6	ACUTE DERMAL IRRITATION STUDY
46783507 VOLUME 82669-R-7	REQUEST FOR WAIVERS OF SPECIFIC DATA REQUIREMENTS
46783508 VOLUME 82669-R-8	SKIN SENSITIZATION STUDY
46783509 VOLUME 82669-R-9	PRODUCT PERFORMANCE
VOLUME SBFWR	SMALL BUSINESS FEE WAIVER REQUEST

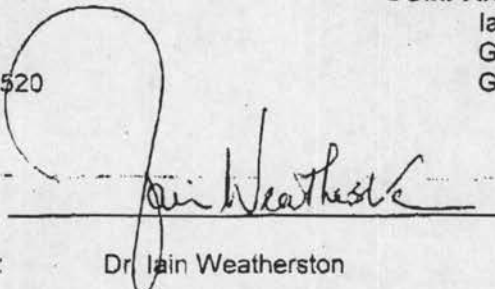
COMPANY NAME

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

COMPANY AGENT

Iain Weatherston, Technology Sciences
Group Inc. 4061 N. 156th Drive,
Goodyear, AZ 85338

AGENT SIGNATURE

March 7, 2006

COMPANY CONTACT:

Dr. Iain Weatherston

TELEPHONE:

623-535-4060

E-MAIL:

jatzkatz@qwest.net

Subject: Re: Fw: [Fwd: Re: HOMES L.L.C. Submission]

From: jazkatz <jazkatz@qwest.net>

Date: Wed, 29 Mar 2006 11:33:23 -0700

To: Hollis.Linda@epamail.epa.gov

CC: reilly.sheryl@epamail.epa.gov

(3 pages)

703-308-7026

Dear Linda:

Thanks for your e-mail and explanation.

I hope to have originals of most of the offending MSDS and better copies of the rest by late next week so I will have three copies of the new Volume 82660-R-2 back into 86-5 before the end of the first full week of April..

For your records I am sending you a copy of the 86-5 analysis report I received.

Also, in your letter the application date is given as December 4, 2005 but should actually be March 9, 2006.

Best regards,

Iain

Hollis.Linda@epamail.epa.gov wrote:

Dear Iain:

I received this 86-5 failure package on 3/26/06. I did not fax you or email you a 86-5 letter. This package was originally routed to the Registration Division and is still assigned to Registration Division so they may have sent you the 86-5 letter. I am working on getting the package reassigned to BPPD. Meanwhile, I have processed the 86-5 letter and it is attached. BPPD 86-5 letters are electronically signed with my signature. There is no cover letter in the submission that I have and therefore I can not fax it to you. Perhaps the cover letter is in the file jacket which I do not have with me.

Correct, study number 01 was rejected. I looked thru the cited pages. The are in fact illegible, the quality of the copy is poor. The copies look transposed. Since there are so many pages that need to be copied, I would suggest that you resubmit the entire volume. Replacement of so many pages is not acceptable.

Per the letter attached the 75 days for which you have to respond ends on June 14, 2006.

(See attached file: 86-5 Deficiency Ltr.- BPB.wpd)

Regards,

Linda A. Hollis
Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
(703) 308-8733

26 March 2006

Iain Weatherston
HOMS L.L.C
Clayton, NC 27520

*75 due date =
June 14, 2006*

RE: BIO-UD-8SPRAY
EPA Reg.#/File Symbol:82669-E
Application dated: December 4, 2005
Notification of Non-compliance with Pesticide Registration Notice 86-5

Fax sent date: fax number not available on application
Fax number:

Dear Dr. Weatherston:

The Biopesticides and Pollution Prevention Division (BPPD) has received your submission to register the subject product. All or some of the data were rejected our Document Processing Unit because they were not submitted as directed in PR Notice 86-5 and should be reformatted and resubmitted to the Document Processing Unit. A copy of PR Notice 86-5 can be found at our website at: http://www.epa.gov/opppmsd1/PR_Notices/pr86-5.html should you need assistance in making the necessary changes.

If you still want to register this product, the application will be kept open for a period of 75 days to give you an opportunity to respond to this memorandum. If you find that you need more time you must request an extension for a reasonable stated period of time. Extension requests must be made immediately to) at (703) 308-8733.

If you do not comply with this procedure by not responding to this letter or requesting an extension of time to resubmit the information, the Agency may administratively withdraw your application from further consideration. Under the provisions of PR Notice 75-4 of August 27, her. Once this is done, you will have to submit completely new application should you wish to pursue the registration of your product after the application has been withdrawn.

The changes and/or corrections required by you are outlined in the attached EPA Transmittal Letter. You must contact Linda Hollis and indicate and that you will submit the corrected pages via facsimile to: (703) 305-0118. If the changes are excessive, you may wish to

fed-ex or courier the documents to our offices or contact Linda Hollis to arrange to come in to our offices to make the necessary changes. Once all changes have been made, your submission will be forwarded to our Document Processing Unit for PR Notice 86-5 Screening.

Should you have additional questions regarding this matter, the Team Leader for this Biochemical Pesticide Product is Linda Hollis @ hollis.linda@epa.gov.

Sincerely,

Linda Hollis

Linda Hollis, Team Leader
Biopesticides and Pollution Prevention Division
Biochemical Pesticides Branch

Attachment

EPA

4 07 06

26 March 2006

Iain Weatherston
HOMS L.L.C
Clayton, NC 27520

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EPA

4 07 06

2

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Linda Hollis

Linda Hollis, Team Leader
Biopesticides and Pollution Prevention Division
Biochemical Pesticides Branch

Attachment



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 21, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TECHNOLOGY SCIENCES GROUP
HOMS, L.L.C.
4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 09-MAR-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [01]:

* The following page(s) in this study is/are illegible due to the poor quality of the photocopying: 19-46 & 60-119.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 21, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

TECHNOLOGY SCIENCES GROUP
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4061 NORTH 156TH DRIVE
GOODYEAR, AZ 85338-

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...

...

...

...

Receipt for Section 3						
S:	791532	Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No	<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>		
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No			
Application Type:	FFS Waiver Request	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No			
Company:	82669 HOMS, L.L.C.		V			
Risk Manager:	Registration Division, Risk Management Team 7					
Product #:	82669-E	Product Name:	BIO-UD-8 SPRAY			
Override#:						
Me Too		Me Too				
Section3:		Product Name:				
Application Date:	04-Dec-2005	ie	OPP Rec'd Date:	09-Mar-2006	Receipt Content	
Front End Date:	15-Mar-2006	ie	Risk Manager Send Date:			ie
FFS Due Date:			Negotiated Due Date:			
OPP Target Date:						
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>			
Receipt Description:						
FFS Waiver Request		New Ingredient Request Date:				
		New Ingredient Received Date:				
Form A:	<input type="checkbox"/>	Signature Date:		Form B:	<input type="checkbox"/>	
				Signature Date:		

Receipt for Section 3

S: 791523

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: New Registration

Billable: ☒ Yes ☐ No

Company: 82669 HOMES, L.L.C.

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 7

Product #: 82669-E Product Name: BIO-UD-8 SPRAY

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 04-Dec-2005

ic

OPP Rec'd Date: 09-Mar-2006

ic

Front End Date: 15-Mar-2006

ic

Risk Manager Send Date:

ic

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Registration application.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt for Section 3

S: 791523
 Regulatory Type: Product Registration - Section 3
 Application Type: New Registration
 Company: 82669 HOMS, L.L.C. V

Resubmission: ☐ Yes ☒ No

Fee For Service: ☒ Yes ☐ No

Billable: ☒ Yes ☐ No

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 7

Product #: 82669-E Product Name: BIO-UD-8 SPRAY

Override#:

Me Too Section 3: Me Too Product Name:

Application Date: 04-Dec-2005 OPP Rec'd Date: 09-Mar-2006

Front End Date: 15-Mar-2006 Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Registration application.

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

This should go
to BPPD

Diana done! sdh 3/30/06
 Can you charge the
 Risk Manager to BPPD?
 Return receipt to me?
 Mx
 L#
 3/29/06

Fee for Service



This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: _____

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr. 91

Receipt No.

S- 791523

EPA File Symbol/Reg. No.

82669-E

Pin-Punch Date:

3/9/06

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

BLS

Granted:

BLS

Amount Due: \$ _____

Parent/Child Decisions:

82669-E / 82669-R

Reviewer: _____ Date: _____

Remarks:

Front panel

BIO-UD-8 SPRAY

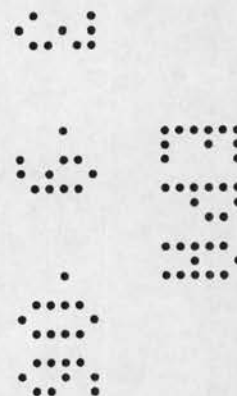
- Repels mosquitoes for 4.5 - 6 hours
- Protects against mosquito borne disease for 4.5 - 6 hours
- Long lasting mosquito repellent
- Block the Bite
- Repels mosquitoes that may transmit West Nile Virus
- Repels ticks that may transmit Lyme Disease
- Repels ticks that may transmit Rocky Mountain Spotted Fever
- Repels mosquitoes that may carry West Nile Virus for 4.5 -6 hours.
- Long lasting protection from mosquitoes that may transmit West Nile Virus
- Reapply every 4.5 to 6 hours
- Repels ticks and other arthropods
- Repels mosquitoes that may transmit West Nile Virus for 4.5 to 6 hours
- Repels ticks and mosquitoes that may transmit disease
- Proprietary botanical formula

ACTIVE INGREDIENT

2-Undecanone [CAS# 112-12-9] 7.75%

OTHER INGREDIENTS 92.25%

TOTAL 100.00%



[See back panel for general instructions and the directions for use]

EPA Registration Number 82669-?

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product

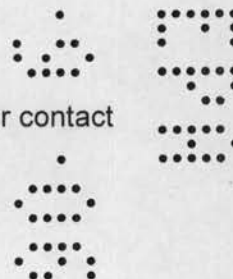
General Instructions: Shake well before using. This bottle is designed to spray upside down. For best results spray on skin every 4.5 - 6 hours. For added protection, apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 6 hours or after swimming, toweling or vigorous activity.

STORAGE AND DISPOSAL

Storage: Store in original container in a cool, dry area inaccessible to children
Disposal: Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.
If partially filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-800-805-BITE (2483) (9am - 5.00 pm Eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520



Front panel

BIO-UD-8 SPRAY

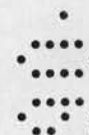
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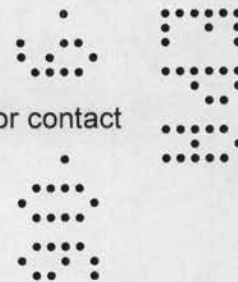
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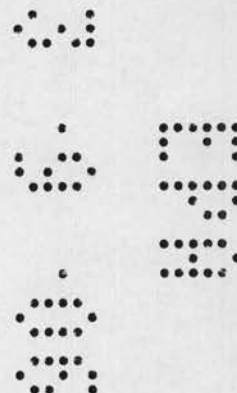
Front panel

BIO-UD-8 SPRAY

- Repels mosquitoes for 4.5 - 6 hours
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- Long lasting mosquito repellent
- Block the Bite
- Repels mosquitoes that may transmit West Nile Virus
- Repels ticks that may transmit Lyme Disease
- Repels ticks that may transmit Rocky Mountain Spotted Fever
- Repels mosquitoes that may carry West Nile Virus for 4.5 - 6 hours.
- Long lasting protection from mosquitoes that may transmit West Nile Virus
- Reapply every 4.5 to 6 hours
- Repels ticks and other arthropods
- Repels mosquitoes that may transmit West Nile Virus for 4.5 to 6 hours
- Repels ticks and mosquitoes that may transmit disease
- Proprietary botanical formula

ACTIVE INGREDIENT

2-Undecanone [CAS# 112-12-9]	7.75%
OTHER INGREDIENTS	92.25%
TOTAL	100.00%



[See back panel for general instructions and the directions for use]

EPA Registration Number 82669-?

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product

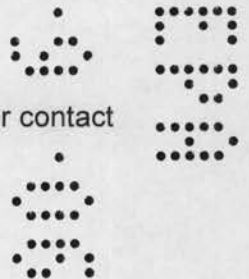
General Instructions: Shake well before using. This bottle is designed to spray upside down. For best results spray on skin every 4.5 - 6 hours. For added protection, apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 6 hours or after swimming, toweling or vigorous activity.

STORAGE AND DISPOSAL

Storage: Store in original container in a cool, dry area inaccessible to children
Disposal: Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.
If partially filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-800-805-BITE (2483) (9am - 5.00 pm Eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520



TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application to register Bio-UD-8 Spray

3. TRANSMITTAL DATE

March 7, 2006

4. LIST OF SUBMITTED VOLUMES

VOLUME 82669-R-1	ADMINISTRATIVE VOLUME: CORRESPONDENCE, LABEL, APPLICATION & CONFIDENTIAL STATEMENT OF FORMULA
Reject (01) VOLUME 82660-R-2	PRODUCT CHEMISTRY
46783502 VOLUME 82669-R-2S	PRODUCT CHEMISTRY - SUPPLEMENTAL VOLUME
46783503 VOLUME 82669-R-3	ACUTE ORAL TOXICITY [LD50 rat] STUDY
46783504 VOLUME 82669-R-4	ACUTE DERMAL TOXICITY [LD50 rat] STUDY
46783505 VOLUME 82669-R-5	ACUTE EYE IRRITATION STUDY
46783506 VOLUME 82669-R-6	ACUTE DERMAL IRRITATION STUDY
46783507 VOLUME 82669-R-7	REQUEST FOR WAIVERS OF SPECIFIC DATA REQUIREMENTS
46783508 VOLUME 82669-R-8	SKIN SENSITIZATION STUDY
46783509 VOLUME 82669-R-9	PRODUCT PERFORMANCE
VOLUME SBFWR	SMALL BUSINESS FEE WAIVER REQUEST

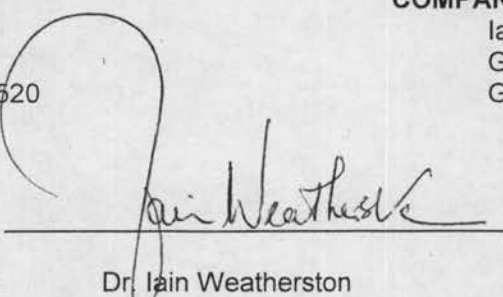
COMPANY NAME

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

COMPANY AGENT

Iain Weatherston, Technology Sciences
Group Inc. 4061 N. 156th Drive,
Goodyear, AZ 85338

AGENT SIGNATURE



March 7, 2006

COMPANY CONTACT:

Dr. Iain Weatherston

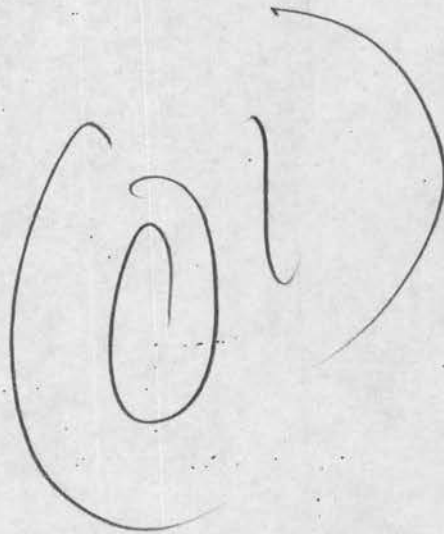
TELEPHONE:

623-535-4060

E-MAIL:

jazkatz@qwest.net

Rejected



Studies

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

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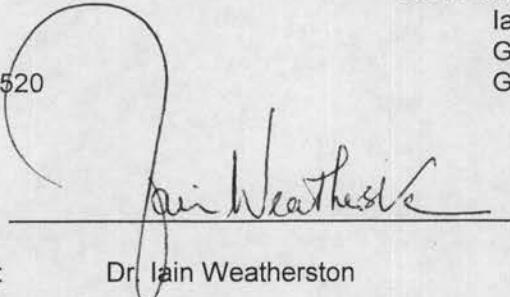
COMPANY NAME

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

COMPANY AGENT

Iain Weatherston, Technology Sciences
Group Inc. 4061 N. 156th Drive,
Goodyear, AZ 85338

AGENT SIGNATURE



March 7, 2006

COMPANY CONTACT:

Dr. Iain Weatherston

TELEPHONE:

623-535-4060

E-MAIL:

jazkatz@qwest.net

TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application to register Bio-UD-8 Spray

3. TRANSMITTAL DATE

March 7, 2006

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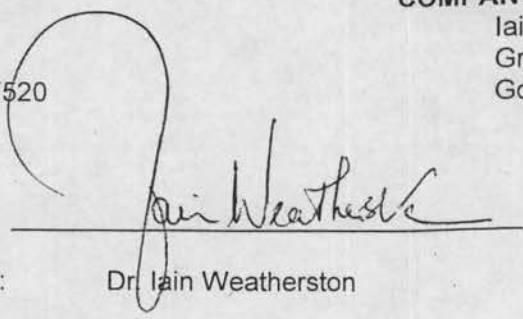
COMPANY NAME

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

COMPANY AGENT

Iain Weatherston, Technology Sciences
Group Inc. 4061 N. 156th Drive,
Goodyear, AZ 85338

AGENT SIGNATURE


Dr. Iain Weatherston

March 7, 2006

COMPANY CONTACT:

TELEPHONE:

623-535-4060

E-MAIL:

jazkatz@qwest.net

TRANSMITTAL DOCUMENT

468049-00

1. NAME AND ADDRESS OF SUBMITTER

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Application to register Bio-UD-8 Spray

3. TRANSMITTAL DATE

March 7, 2006

4. LIST OF SUBMITTED VOLUMES

VOLUME 82669-R-1	ADMINISTRATIVE VOLUME: CORRESPONDENCE, LABEL, APPLICATION & CONFIDENTIAL STATEMENT OF FORMULA
46804901 VOLUME 82660-R-2	PRODUCT CHEMISTRY
46783502 VOLUME 82669-R-2S	PRODUCT CHEMISTRY - SUPPLEMENTAL VOLUME
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VOLUME SBFWR	SMALL BUSINESS FEE WAIVER REQUEST

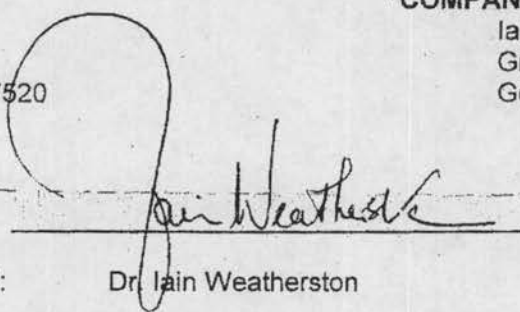
COMPANY NAME

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

COMPANY AGENT

Iain Weatherston, Technology Sciences
Group Inc. 4061 N. 156th Drive,
Goodyear, AZ 85338

AGENT SIGNATURE


Dr. Iain Weatherston

March 7, 2006

COMPANY CONTACT:

TELEPHONE:

623-535-4060

E-MAIL:

jazkatz@qwest.net

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Dr. Sheryl Reilly
Chief, Biochemicals Branch
U.S. EPA - OPP - BPPD
Crystal Mall #2, 9th Floor
1801 South Bell Street
Arlington, VA 22202

February 26, 2006

SUBJECT: Application to register Bio-UD-8 Tropical Spray, a biochemical pest control agent that repels mosquitoes and ticks.

COMPANY: HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

CONTACT: Iain Weatherston
Technology Sciences Group Inc.
[contact information as per letterhead]

PRODUCT: Bio-UD-8 Spray

PRIA CATEGORY: B65

Dear Dr. Reilly:

As agent for, and on behalf of HOMS, L.L.C. I submit for your review and approval this application to register Bio-UD-8I Spray a biochemical pest control agent containing 2-undecanone at 7.75% as the sole active ingredient.

This follows from the teleconference held on August 30, 2005, the minutes of which are attached to this letter. As discussed at the meeting HOMS will purchase a registered manufacturing-use product from

However, the 2-undecanone database at the Agency does not support a Domestic and Human use pattern and hence this application addresses the supplemental information required, namely a 90-day dermal toxicity study and an immunotoxicity study. Both of these requirements are addressed in Volume 82669-R-7 through waiver requests and an exposure assessment prepared by Dr. Beth Mileson after discussions with Dr. Roger Gardner.

In addition to this letter, this volume [82669-R-1} contains

- fully executed pesticide application form [8570-1] obtained from website
- certification with respect to data citation [8570-34]
- formulators exemption statement [8570-27]
- copy of letter of authorization from [REDACTED]
- Confidential Statement of Formula
- Draft label (five copies, one bound into this volume and four loose)

Product ingredient source information may be entitled to confidential treatment*

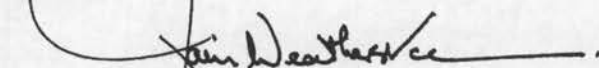
In addition to this volume, the applications consists of:

Volume 82669-R-2	-	Product chemistry
Volume 82669-R-2S		Product chemistry - supplemental volume
Volume 82669-R-3		Acute oral toxicity [LD50 rat] study
Volume 82669-R-4		Acute dermal toxicity [LD50 rat] study
Volume 82669-R-5		Acute eye irritation study
Volume 82669-R-6		Acute dermal irritation study
Volume 82669-R-7		Waivers of specific data requirements
Volume 82669-R-8		Skin sensitization study
Volume 82669-R-9		Product performance
Volume SBFWR		Small Business Fee Waiver Request

PRIA considerations were discussed during the pre-application teleconference and the consensus was that the two applications should be submitted simultaneously as PRIA Category B65 (parent/child type application). The spray product application being the parent since it is the one that addresses the extra data requirements necessary to extend the use of 2-undecanone to include the Domestic and Human use pattern

Should you have any questions, or require further information, please do not hesitate to contact me by e-mail (jazkatz@qwest.net) or by phone at 623-535-4060.

Sincerely,



Iain Weatherston

attachment\ copy of minutes from August 30, 2005 teleconference.

CONTENTS

CONFIDENTIALITY CLAIMS	2.
GOOD LABORATORY PRACTICES STATEMENT	3.
CONTENTS	4.
LETTER OF INTRODUCTION	5.
MINUTES FROM THE AUGUST 30 PRE0-APPLICATION TELECONFERENCE	7..
APPLICATION FORM [EPA Form 8570-1]	10.
PLACE HOLDER PAGE	11.
CERTIFICATION WITH RESPECT TO DATA CITATION [EPA Form 8570-34]	24.
LETTER OF AUTHORIZATION FROM MGK COMPANY ...	25.
FORMULATOR'S EXEMPTION STATEMENT [EPA Form 8570-27].....	26.
DATA MATRIX [EPA Form 8570-35]	27.
DRAFT LABEL	31.
CONFIDENTIAL ATTACHMENT	
COVER PAGE	1.
CROSS REFERENCE PAGES	2.
CONFIDENTIAL STATEMENT OF FORMULA	3.

CONFIDENTIALITY CLAIMS

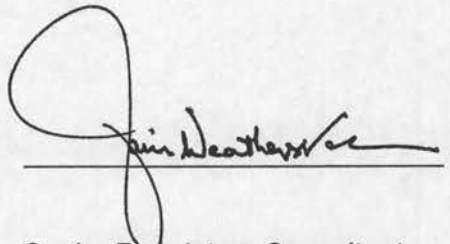
STATEMENT OF DATA CONFIDENTIALITY

Information claimed confidential on the basis of its falling within the scope of FIFRA §10[d][1][A], [B] or [C] has been moved to a confidential attachment and is cited by cross reference numbers in the body of the text.

COMPANY: HOMS L.L.C.

AGENT: Iain Weatherston

SIGNATURE:

A handwritten signature in black ink, appearing to read "Iain Weatherston", is written over a horizontal line.

TITLE: Senior Regulatory Consultant

DATE: February 26, 2006

APPLICATION TO REGISTER BIO-UD-8 SPRAY
A BIOCHEMICAL PEST CONTROL AGENT THAT REPELS MOSQUITOES AND TICKS

End-Use Product
EPA File Symbol 82669-?

VOLUME 82669-R-1
ADMINISTRATIVE MATERIALS, CORRESPONDENCE, APPLICATION, LABEL AND
CONFIDENTIAL STATEMENT OF FORMULA

DATA REQUIREMENTS
40 CFR 152.50

PRIA Category B65

AUTHOR
Iain Weatherston

DATE COMPLETED
February 26, 2006

SUBMITTED BY
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338

ON BEHALF OF
HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520



GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this report **do not fall under** the requirements of 40 CFR 160.

PLACE HOLDER PAGE

CROSS REFERENCE NUMBER [1]

The cross reference number noted on this page is used in place of the following whole page(s):

DELETED PAGE(S): Found in the confidential attachment

PAGE(S): 12 - 23

REASON FOR DELETION: Confidential Statement of Formula

FIFRA REFERENCE: § 10 [d][1][C]

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number HOMS LLC., POB 724, Clayton, NC 27520 919-550-0409	EPA Registration Number/File Symbol 82669-2
Active Ingredient(s) and/or representative test compound(s) 2-Indecanone (methyl nonyl ketone)	Date December 4, 2005
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) INDOOR - 13. Domestic and human use	Product Name BIO-UD-8 SPRAY

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date
Dec. 4, 2005Typed or Printed Name and Title
Iain Weatherston - Senior Regulatory Consultant



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address HOMS L.L.C. P.O. Box 724 Clayton, NC 27520	EPA File Symbol/Registration Number 82669-?
	Product Name BIO-UD-8 SPRAY
	Date of Confidential Statement of Formula (EPA Form 8570-4) 12/04/2005

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

2- Undecanone

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

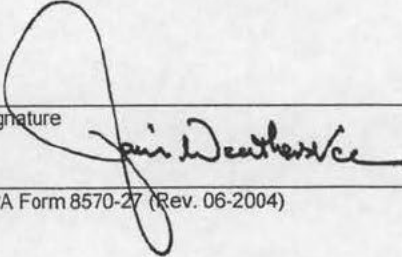
(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
2-Undecanone		
<i>*Product ingredient source information may be entitled to confidential treatment*</i>		
Signature 	Name and Title Iain Weatherston	Date 12/04/2005



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

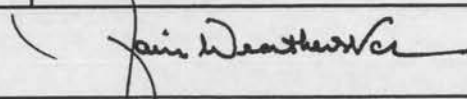
Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date December 20, 2005	EPA Reg No./File Symbol 82669-?	Page 1 of 2
Applicant's/Registrant's Name & Address HOM L.L.C., P.O. Box 724, Clayton, NC 27520		Product BIO-UD-8 SPRAY

Ingredient 2-UNDECANONE

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 880.1100	Product identity & composition	Vol 82669-R-2	HOMS L.L.C.	Own	this submission
OPPTS 880.1200	Starting materials and formulation process	Vol 82669-R-2	HOMS L.L.C.	Own	this submission
OPPTS 880.1400	Discussion of formation of impurities	Vol 82669-R-2	HOMS L.L.C.	Own	this submission
OPPTS 830.1750	Certification of limits	Vol 82669-R-2	HOMS L.L.C.	Own	this submission
OPPTS 830.1800	Enforcement analytical methods	Vol 82669-R-2	HOMS L.L.C.	Own	this submission
OPPTS 830.6000/7000	Chemical/physical characteristics	Vol 82669-R-2	HOMS L.L.C.	Own	this submission
OPPTS 830.6000/7000	Chemical/physical characteristics	V 82669-R-2S	HOMS L.L.C.	Own	this submission
OPPTS 870.1100	Acute oral LD50 (rat)	Vol 82669-R-3	HOMS L.L.C.	Own	this submission
OPPTS 870.1200	Acute dermal LD50 (rat)	Vol 82669-R-4	HOMS L.L.C.	Own	this submission
OPPTS 870.1300	Acute inhalation LD50 (rat)	V 82669-R-7	HOMS L.L.C. (waiver request)	Own	this submission
OPPTS 870.2400	Acute eye irritation	Vol 82669-R-5	HOMS L.L.C.	Own	this submission
OPPTS 870.2500	Acute dermal irritation	Vol 82669-R-6	HOMS L.L.C.	Own	this submission
OPPTS 870.2600	Dermal sensitization	Vol 83669-R-8	HOMS L.L.C. see letter of introduction	Own	this submission is in progress
OPPTS 870.3250	90 Day dermal toxicity	V 82669-R-7	HOMS L.L.C. (waiver request)	Own	this submission
OPPTS 880.3550	Immunotoxicity	V 82669-R-7	HOMS L.L.C. (waiver request)	Own	this submission
Signature 			Name and Title Iain Weatherston Senior Regulatory Consultant		Date 12/20/2005

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Date December 20, 2005

EPA Reg No./File Symbol 82669-?

Page 2 of 2

Applicant's/Registrant's Name & Address HOM L.L.C., P.O. Box 724, Clayton, NC 27520

Product	BIO-UD-8 SPRAY
---------	----------------

Ingredient 2-UNDECANONE

[illegible]

Front panel

BIO-UD-8 SPRAY

- Repels mosquitoes for 4.5 - 6 hours
- Protects against mosquito borne disease for 4.5 - 6 hours
- Long lasting mosquito repellent
- Block the Bite
- Repels mosquitoes that may transmit West Nile Virus
- Repels ticks that may transmit Lyme Disease
- Repels ticks that may transmit Rocky Mountain Spotted Fever
- Repels mosquitoes that may carry West Nile Virus for 4.5 -6 hours.
- Long lasting protection from mosquitoes that may transmit West Nile Virus
- Reapply every 4.5 to 6 hours
- Repels ticks and other arthropods
- Repels mosquitoes that may transmit West Nile Virus for 4.5 to 6 hours
- Repels ticks and mosquitoes that may transmit disease
- Proprietary botanical formula

ACTIVE INGREDIENT

2-Undecanone [CAS# 112-12-9] 7.75%

OTHER INGREDIENTS 92.25%

TOTAL 100.00%

[See back panel for general instructions and the directions for use]

EPA Registration Number 82669-?

EPA Establishment Number xxxxx-xx-xx

Net Contents: 4.0 oz 6.7 oz

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Read all directions before using this product

General Instructions: Shake well before using. This bottle is designed to spray upside down. For best results spray on skin every 4.5 - 6 hours. For added protection, apply to clothing. Do not apply to lips and keep out of eyes. Do not apply to the hands of young children. For continuous protection against target pests apply every 6 hours or after swimming, toweling or vigorous activity.

STORAGE AND DISPOSAL

Storage: Store in original container in a cool, dry area inaccessible to children
Disposal: Empty container by using the product according to label directions, then dispose of container in the trash or offer for recycling if available. Do not reuse the container.
If partially filled: Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

Questions or comments. Call 1-800-805-BITE (2483) (9am - 5.00 pm Eastern time) or contact HOMS at CustomerService@homs.com

HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

APPLICATION TO REGISTER BIO-UD-8 SPRAY
A BIOCHEMICAL PEST CONTROL AGENT THAT REPELS MOSQUITOES AND TICKS

End-Use Product
EPA File Symbol 82669-?

VOLUME 82669-R-1CA
CONFIDENTIAL ATTACHMENT

DATA REQUIREMENTS
40 CFR 152.50

AUTHOR
Iain Weatherston

DATE COMPLETED
February 26, 2006

SUBMITTED BY
Technology Sciences Group Inc.
4061 North 156th Drive
Goodyear, AZ 85338

ON BEHALF OF
HOMS L.L.C.
P.O. Box 724
Clayton, NC 27520

CROSS REFERENCE PAGE

CROSS REFERENCE NUMBER: [1]

The cross-reference number noted on this page is used in place of the following whole page(s):

DELETED PAGE(S): Found in the confidential attachment

PAGE(S): 12 - 23

REASON FOR THE DELETION: Confidential Statement of Formula

FIFRA: § 10 [d][1][C]



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 82669- A E		2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) HOMS L.L.C. / BIO-UD-8 SPRAY		PM# 88 07	
5. Name and Address of Applicant (Include ZIP Code) HOMS, L.L.C. P.O. Box 724 Clayton, NC 27520 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
Section - II			
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____	
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input type="checkbox"/> "Me Too" Application.	
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.)			
PRIA Category B65			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container
		If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4 oz and 6.7 oz.	
5. Location of Label Directions <input checked="" type="checkbox"/>			
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
<input checked="" type="checkbox"/> Other: silkscreen			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Iain Weatherston		Title Senior Regulatory Consultant	Telephone No. (Include Area Code) 623-535-4060 PAX 222-872-0745
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Senior Regulatory Consultant	
4. Typed Name Iain Weatherston		5. Date December 4, 2005	

1940-1941



1940-1941



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address HOMS L.L.C. P.O. Box 724 Clayton, NC 27520	EPA File Symbol/Registration Number 82669-?
	Product Name BIO-UD-8 SPRAY
	Date of Confidential Statement of Formula (EPA Form 8570-4) 12/04/2005

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

2- Undecanone

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
2-Undecanone		
<i>*Product ingredient source information may be entitled to confidential treatment*</i>		
Signature 	Name and Title Iain Weatherston	Date 12/04/2005



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4. Company/Product (Name) HOMS L.L.C. / BIO-UD-8 SPRAY		PM# 99	
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2. Signature 			
3. Title Senior Regulatory Consultant			
4. Typed Name Iain Weatherston		5. Date December 4, 2005	

Technology Sciences Group Inc.
Arizona: Regulatory Division
4061 North 156th Drive
Goodyear, AZ 85338
Phone: (623) 535-4060
FAX (623) 535-4061
E-Mail: jazkatz@qwest.net



Iain Weatherston, Ph.D.
Senior Regulatory Consultant
Pesticide Division

Andrew Bryceland
EPA - OPP - BPPD - BB
Crystal Mall #2, 9th Floor
1801 South Bell Street
Arlington, VA 22202

September 3, 2004

SUBJECT: Minutes from the pre-application teleconference held on Tuesday, August 30, 2005 from 10.15 - 11.30 am eastern time

COMPANY: HOMS L.L.C.
P.O. Box 724
Clayton Center
Clayton, NC 27520

CONTACT: Iain Weatherston, Ph.D.
Technology Sciences Group Inc.
[contact information as per letterhead]

COPY

Dear Andrew:

The following is my recollection of our teleconference, and these notes have been reviewed by both Beth Milesen and Allen Jones.

The teleconference took place on Tuesday August 30, 200 from 10.15 am to 11.30 am, eastern time. The attendees were:

Representing BPPD

Sheryl Reilly
Linda Hollis
Angela Gonzalez
Roger Gardiner
Andrew Bryceland

Representing HOMS

Beth Milesen (TSG) at BPPD
Allen Jones (HOMS) by telephone
Iain Weatherston (TSG) by telephone

The meeting was chaired by Andrew Bryceland who indicated that the background document previously sent to the Agency could act as the agenda, and he asked Weatherston to speak to the issues. Weatherston indicated that this was actually the third meeting between HOMS and the Agency regarding the registration of 2-undecanone containing repellent products to be used to mitigate mosquitoes and ticks as pests on humans. The previous two meeting were really not very satisfactory, partly because of the number of products and their several use patterns which were attempted to be covered, and that this meeting the focus should be only two products (one a lotion and the other a spray), both containing 7.5% 2-undecanone in the same [REDACTED]

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Inert ingredient information may be entitled to confidential treatment

Andrew Bryceland
September 3, 2005
Page 2.

1995] does not support a Domestic and Human use pattern, so the first product application submission will address the supplemental information required. On review of the RED and 40 CFR 158.690 the data lacking is toxicity data, namely immunotoxicity and 90-day dermal toxicity data.

Beth Milesen indicated that the data from the 21-day dermal study [RED] together with the current level of exposure to 2-undecanone from food and beverage uses should probably be enough for the basis of a request to waive the 90-day dermal study. Roger Gardner said that a 90-day dermal study is not necessary given that a 21 -day dermal study is available, but the problem with the 21-day study is that no systemic effects were observed at the highest dose tested and an actual endpoint may be necessary to form the basis of a risk assessment.. He suggested that a second 21-day dermal study be performed at a limit dose if the estimated exposure to 2-undecanone does not provide an acceptable margin of error (i.e. a MOE of 100 or greater) given the NOAEL at the high dose tested in the current 21-day dermal study. Repeated application of a limit dose of 2-undecanone will likely result in significant skin irritation which may facilitate dermal absorption and could result in an increase in systemic toxicity. It was further suggested that if the 21-day dermal limit dose study resulted in an increase in dermal absorption and toxicity, a 90-day oral study could be done to characterize the dermal absorption in the absence of irritation.

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Since Weatherston previously mentioned the label, Andrew indicated that although a full label review had not been done, there were several claims or marketing statements on the draft label which would not be allowable, these included any comparative statement regarding efficacy against another registered product or active ingredient, general terms such as "other nuisance and biting flies" unless data is actually submitted showing efficacy against an array of species.

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September 3, 2005
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There being no further discussion items Weatherston thanked the BPPD personnel on behalf of HOMS and the teleconference ended about 11. 30 am.

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Page 2.

1995] does not support a Domestic and Human use pattern, so the first product application submission will address the supplemental information required. On review of the RED and 40 CFR 158.690 the data lacking is toxicity data, namely immunotoxicity and 90-day dermal toxicity data.

Beth Milesen indicated that the data from the 21-day dermal study [RED] together with the current level of exposure to 2-undecanone from food and beverage uses should probably be enough for the basis of a request to waive the 90-day dermal study. Roger Gardner said that a 90-day dermal study is not necessary given that a 21-day dermal study is available, but the problem with the 21-day study is that no systemic effects were observed at the highest dose tested and an actual endpoint may be necessary to form the basis of a risk assessment.. He suggested that a second 21-day dermal study be performed at a limit dose if the estimated exposure to 2-undecanone does not provide an acceptable margin of error (i.e. a MOE of 100 or greater) given the NOAEL at the high dose tested in the current 21-day dermal study. Repeated application of a limit dose of 2-undecanone will likely result in significant skin irritation which may facilitate dermal absorption and could result in an increase in systemic toxicity. It was further suggested that if the 21-day dermal limit dose study resulted in an increase in dermal absorption and toxicity, a 90-day oral study could be done to characterize the dermal absorption in the absence of irritation.

COPY BPRD stated that a waiver request could be submitted to satisfy the immunotoxicity requirement based on the fact that 2-undecanone stimulates the immune system while the immunotoxicity study is intended to detect immune depression.

The next issue discussed was the oral exposure of children who could possibly lick the materials from their arms. Beth indicated that much attention has been placed to studying "activities" of children and "arm licking" does not appear to be an important behavior of young children. Based on the NOEL for systemic effects in the 21-day dermal study, Beth had done a quick and dirty exposure calculation based on application rates and repeated applications and come to the conclusion that this would not be of concern. Roger, indicated that he would like to see Beth's calculations and requested that she send them into him electronically. The products will be labeled such that the directions for use will indicate that they should **not be applied to the hands of young children**, this is to mitigate any transfer of the materials from the hands to food or snacks and into the young child's mouth, or direct access to the mouth from thumb sucking or putting their fingers into their mouths.

It had been noticed by TSG that the registrant of the p-menthane-3,8-diol products had submitted a human sensitization study and Weatherston wondered if HOMS would likewise be expected to submit such a study, Roger answered by saying that the EPA had not requested such a study in the PMD case and would not request one for 2-undecanone. He also spoke to the current situation regarding the testing of insecticides on human subjects and the political discussions that were taking place as part of the appropriations process.

Since Weatherston previously mentioned the label, Andrew indicated that although a full label review had not been done, there were several claims or marketing statements on the draft label which would not be allowable, these included any comparative statement regarding efficacy against another registered product or active ingredient, general terms such as "other nuisance and biting flies" unless data is actually submitted showing efficacy against an array of species.

Andrew Bryceland

September 3, 2005
Page 3.

There was some discussion about "Proprietary botanical formula" and it was agreed that this was probably acceptable. Andrew and Linda indicated that it is best to have clear, distinct claims that the study data support so that the registration is not held up due to an extensive dialogue between BPPD and the applicant to resolve verbiage. Andrew said that it is better to initially register the product with clear claims, then once it is registered and more data are developed claims may be added by label amendments.

Product chemistry was the next subject discussed, the background document had indicated that since each product contained 7.5% undecanone and the same list of other ingredients that only one set of physical/chemical characteristics would be submitted, Angela pointed out that since [REDACTED] was in one formula but not the other maybe two sets of physical/chemical characteristics would be required. Allen Jones said that possibly the [REDACTED] had been omitted since it was actually in both formulations. Sheryl indicated that the formulation lists submitted would be unacceptable since some of the ingredients were only identified by trade names. Iain assured her that the CSF's would be properly constructed and contain both the chemical name and the CAS number in addition to the trade names. Iain also brought up the issue of [REDACTED] which although both an active ingredient, and exempt from tolerance is not on any of the EPA inert lists. After some discussion about possible scenarios the matter was tabled till it could be determined if a suitable replacement inert could be found. After the end of the meeting Weatherston found that [REDACTED] which would be a satisfactory substitute is in fact on EPA Inerts List 4B. Angela also brought up the matter of fragrance, since both draft formulations submitted with the background document listed at [REDACTED] "fragrance/parfum" and indicated that this was unsatisfactory since the material must be named. Allen Jones indicated that more than one fragrance was likely to be used, Weatherston pointed out that this should not be an issue since if there were four fragrances then the applications would contain one basic formulation and three alternate ones.

The last item to be discussed was the PRIA category of the submissions, Weatherston said that he thought the first submission, the one which addressed the 2-undecanone requirements as well as end-use requirements for one of the products would be classified B 65 which is a new use, non food and then if he waited until he received the MRID numbers for submitted studies he could then make the second end-use product submission as a B 67. In the ensuing discussion Linda and Sheryl indicated that provided both applications were submitted simultaneously then they would qualify for a parent/child type application and only one fee [\$5250] would be necessary and that both applications would be in review concurrently with an expected review time of 6 months.

There being no further discussion items Weatherston thanked the BPPD personnel on behalf of HOMS and the teleconference ended about 11. 30 am.

That Andrew is our collective recollections of the teleconference, should you or your colleagues disagree with the notes, believe there to be omissions or wish clarification, please let me know so that our records can be corrected.

Sincerely,

COPY
Iain Weatherston

PLACE HOLDER PAGE

CROSS REFERENCE NUMBER [1]

The cross reference number noted on this page is used in place of the following whole page(s):

DELETED PAGE(S): Found in the confidential attachment

PAGE(S): 12 - 23

REASON FOR DELETION: Confidential Statement of Formula

FIFRA REFERENCE: § 10 [d][1][C]

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of DataApplicant's/Registrant's Name, Address, and Telephone Number
HOMS LLC., POB 724, Clayton, NC 27520 919-550-0409EPA Registration Number/File Symbol
82669-?Active Ingredient(s) and/or representative test compound(s)
2-Indecanone (methyl nonyl ketone)Date
December 4, 2005General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
INDOOR - 13. Domestic and human useProduct Name
BIO-UD-8 SPRAY

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date
Dec. 4, 2005Typed or Printed Name and Title
Iain Weatherston - Senior Regulatory Consultant

